

# Exhibit 6

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1 UNITED STATES DISTRICT COURT

2 DISTRICT OF NEW JERSEY

3 Case No. MDL No. 16-2738 (MAS) (RLS)

5 IN RE: JOHNSON & JOHNSON

6 TALCUM POWDER PRODUCTS

7 MARKETING, SALES PRACTICES,

8 AND PRODUCTS LIABILITY

9 LITIGATION

10 -----

11  
12 The deposition of CHRISTIAN MERLO, M.D. was held  
13 on Friday, June 14, 2024, at 100 South Charles Street,  
14 Suite 1600, Baltimore, Maryland 21201, commencing at  
15 9:01 A.M., before Faith Kelchaw, Stenographic Court  
16 Reporter and Notary Public.

17  
18  
19 REPORTED BY: Faith Kelchaw, Stenographic Reporter  
20  
21

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2	CHRISTOPHER TISI, ESQUIRE		2 WITNESS PAGE
3	Levin Papantonio Rafferty		3 CHRISTIAN MERLO, M.D.
4	316 South Baylen Street		4 By Mr. Tisi 7, 267, 269
5	Pensacola, FL 32502		5 By Mr. Bishop 268
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17	Johnson & Johnson and the Deponent		17
18			18
19			19
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1	CHRISTIAN MERLO, M.D.,		
2	having first been duly sworn, testified as follows:		
3	EXAMINATION BY MR. TISI:		
4	Q. Good morning, Dr. Merlo. I am Chris Tisi.		
5	I represent the MDL plaintiffs in this case. With me is		
6	Michelle Parfitt to my right here, and she represents		
7	the New Jersey plaintiffs. We're here to take your		
8	supplemental deposition.		
9	You understand that to be true; right?		
10	A. I do. Good morning.		
11	Q. Good morning.		
12	I am going to hand you -- mark this -- several		
13	exhibits that I'm going to start out the deposition		
14	today and mark them. All right. Let's see if we can		
15	get going.		
16	Just by way of foundation, you issued an expert		
17	report on the issue of general causation.		
18	You know what that means; right?		
19	A. Yes.		
20	Q. Yeah. You issued a report on general causation		
21	in the talcum powder litigation in February of 2019.		

1 they used the flawed methodology and that talc doesn't 2 cause ovarian cancer? 3 A. That cosmetic talc does not cause ovarian 4 cancer. 5 Q. Now, in 2024, in April, you issued an updated 6 general causation report in the Carl and Balderrama 7 cases pending in the state of New Jersey; true? 8 A. That's correct. 9 Q. Okay. And while you have some opinions on the 10 Balderrama case, the primary purpose of that report was 11 to update your opinions with regard to general causation 12 and address additional concerns of plaintiffs' experts; 13 true? 14 A. That's correct. I did review some case-specific 15 materials regarding them, mainly to the look for markers 16 of asbestos in radiology films. 17 Q. Right. But -- yes. And we'll talk about them. 18 But, generally speaking, the vast bulk of your 19 report is basically to update your opinions both as to 20 the fact -- your opinion that talc does not cause 21 ovarian cancer and that plaintiffs' experts still do not	Page 10 1 Q. And I'd like to attach that report as 2 Exhibit Number 2. 3 (Deposition Exhibit 2 was marked.) 4 THE WITNESS: Thanks. 5 BY MR. TISI: 6 Q. Yeah. I'm sorry. I don't want to throw it at 7 you, but I don't want to trip over the -- 8 A. That's okay. 9 Q. -- court reporter here. 10 And Exhibit Number 2 is your updated MDL report; 11 correct? 12 A. Let me just look at one section and I'll be able 13 to tell you that. 14 Q. Well, the cover sheet says -- 15 A. I mean, it -- yes. 16 Q. I'll represent to you -- how about if 17 I represent to you that that is your MDL report. 18 A. That's correct. Yeah. 19 Q. Okay. And you do know that this is -- this 20 report was originally due on approximately May 21st, but 21 you were given an extra seven days to address a new
Page 11 1 apply an appropriate methodology; true? 2 A. Yeah. I think the general update to my report 3 was, is there any other evidence out there that I would 4 need to consider to -- to either alter my opinion or 5 maintain my opinion. 6 Q. Okay. 7 A. And that is what the bulk of the difference in 8 my report is. 9 Q. And I'm going to hand you what I'm going to have 10 marked as Exhibit Number 1, which is the Carl and 11 Balderrama report. I've given a copy to counsel. 12 (Deposition Exhibit 1 was marked.) 13 BY MR. TISI: 14 Q. Is this the Carl -- Exhibit 1 going to be your 15 Carl and Balderrama report? 16 A. Yes. 17 Q. Okay. And on May 28th, 2024, you issued an 18 updated general causation report in the federal MDL 19 proceedings, proceeding in the federal court in 20 New Jersey as well; correct? 21 A. That's correct.	Page 13 1 study that were published by the authors from the NIEHS 2 regarding talcum powder; true? 3 A. Is this the O'Brien 2024 study? 4 Q. Correct. 5 A. Yes. That's correct. 6 Q. Okay. And so the primary difference, other than 7 the small case-specific issues that we'll talk about 8 later, was to address the new study which we'll call 9 O'Brien 2024; correct? 10 MR. BISHOP: In comparison to the Carl report? 11 MR. TISI: Yes. 12 THE WITNESS: That -- yes. That is correct. 13 BY MR. TISI: 14 Q. Okay. And I'm going to have marked -- and you 15 can keep this out as well. This is the 2024 O'Brien 16 study; correct? Which we marked as Exhibit Number 3. 17 A. That's correct. 18 (Deposition Exhibit 3 was marked.) 19 BY MR. TISI: 20 Q. All right. So let's talk generally, if we 21 could -- would you agree that, putting aside the

<p style="text-align: right;">Page 14</p> <p>1 specific updated studies in your 2024 reports in the MDL      2 and Carl and Balderrama, that you applied the same      3 methodology that you applied in your 2019 report?</p> <p>4 A. The methodology that I would use in forming an      5 opinion between an exposure and an outcome is that      6 methodology, and that methodology has not changed since      7 2019.</p> <p>8 Q. Okay. So there really are no methodologic      9 differences between your report. It's just      10 incorporating new data that has become available since      11 2024 -- 2019?</p> <p>12 A. That's correct.</p> <p>13 Q. All right. So, for example, you still applied      14 the same Bradford Hill considerations in considering --      15 and considering bias, confounding chance, with respect      16 to published studies. The same methodology you did in      17 2019, you did in 2024?</p> <p>18 A. I considered the same Bradford Hill framework in      19 the update of this report --</p> <p>20 Q. Okay.</p> <p>21 A. -- when compared to 2019.</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. You've looked at Smith-Bindman. You've looked      2 at McTiernan. You've looked at Siemiatycki. You've      3 looked at the same people you looked at before?</p> <p>4 A. That's correct.</p> <p>5 Q. And, basically, they had the same methodology      6 that they used before that you considered to be flawed,      7 but they applied the same methodology as well; true?</p> <p>8 A. Well, I haven't really looked at it that way.</p> <p>9 But my opinion of their -- their opinions has not      10 changed since 2019.</p> <p>11 Q. Right.</p> <p>12 So from a methodologic perspective, they use the      13 same methodology which you disagree with that you      14 critiqued the first time?</p> <p>15 I just want to make sure that I don't need to go      16 back and talk about methodology questions about, for      17 example, the role of statistical significance or      18 anything like that.</p> <p>19 That's all the same as it was before?</p> <p>20 A. Yes. That's correct.</p> <p>21 Q. Okay. All right. And your criticisms of their</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Okay. And you applied the very same kinds of      2 considerations? Nothing's changed with respect to your      3 considerations of bias and statistical significance and      4 confounding and all the things we talked about last      5 time?</p> <p>6 A. Yeah. Those wouldn't change in my opinion or in      7 my methodology. Those aren't part of the Bradford Hill      8 framework, but they are part of the report and would be      9 part of my formulation of an opinion, and that has not      10 changed since 2019.</p> <p>11 Q. Now let's flip the script a little bit and talk      12 about -- you had reviewed plaintiffs' experts'      13 supplemental reports as well; correct?</p> <p>14 A. That's correct.</p> <p>15 Q. Which ones did you review? Do you remember?</p> <p>16 A. Oh, I would have to look. I was supplied many.</p> <p>17 Q. Yeah. And I'm not going to ask you to name      18 every one of them.</p> <p>19 But you reviewed them, particularly the ones      20 that you looked at for your 2019 reports; right?</p> <p>21 A. That's correct.</p>	<p style="text-align: right;">Page 17</p> <p>1 methodology in 2019 is the same criticisms that you hold      2 today? In fact, if I could be so bold as to suggest      3 your report is basically an update of the -- of what you      4 did in 2019?</p> <p>5 MR. BISHOP: Objection to the form. The report      6 speaks for itself.</p> <p>7 Go ahead.</p> <p>8 THE WITNESS: I mean, my report is -- was made      9 to address the -- if there were any further      10 epidemiologic studies or any further epidemiologic      11 evidence that would alter my opinion.</p> <p>12 BY MR. TISI:</p> <p>13 Q. So I just want to be clear I want because I want      14 to take something off the table; right? I want to make      15 sure we're not talking about -- from a methodologic      16 perspective, the methodology that you used is exactly      17 the same as you used in 2019; true?</p> <p>18 MR. BISHOP: Object to the form. Vague.</p> <p>19 Overbroad.</p> <p>20 THE WITNESS: If I look at my report, it does      21 describe the methodology, and that part of the report</p>

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1 has not changed. 2 BY MR. TISI: 3 Q. Right. 4 And from the plaintiffs' experts' perspective, 5 you've reviewed their reports, and, generally speaking, 6 their methodology has not changed either. They're just 7 addressing, like you did, the new and updated studies; 8 true? 9 MR. BISHOP: Same objection. 10 THE WITNESS: In general, that would be my -- 11 BY MR. TISI: 12 Q. Okay. 13 A. -- my opinion. Yes. 14 Q. All right. Let's switch topics a little bit. 15 Before we talk about your report, I want to talk 16 a little bit about what you've done professionally since 17 2019. 18 I'm going to attach -- provide you with 19 Exhibit Number 4, which is your updated curriculum 20 vitae. 21 (Deposition Exhibit 4 was marked.)	1 A. I am, yes. 2 Q. You're not board certified today in oncology or 3 gynecology; true? 4 A. I am not board certified in oncology or 5 gynecology. 6 Q. Okay. Do you know whether or not the -- 7 Johns Hopkins holds you out as an expert in either 8 gynecology or oncology? 9 A. So I'm not a gynecologist or an oncologist. My 10 assumption would be that Johns Hopkins would not 11 consider me either of those things. 12 Q. All right. Johns Hopkins considers you an 13 expert in or somebody -- as a professor in pulmonology; 14 true? 15 MR. BISHOP: Objection to form. Vague. 16 Overbroad. 17 THE WITNESS: So I'm a pulmonologist. I'm also 18 a critical care physician, and I also have expertise in 19 internal medicine as well as epidemiology. 20 BY MR. TISI: 21 Q. I'm going to show you -- I pulled this from the
Page 19	Page 21
1 MR. BISHOP: Thank you. 2 BY MR. TISI: 3 Q. You are still an associate professor at Hopkins; 4 true? 5 A. I am, yes. 6 Q. Okay. Is that the same as being adjunct 7 professor? 8 A. No. No, it's not. 9 Q. Okay. And does this CV accurately reflect your 10 expert -- your education and expertise as of today? 11 A. I would say so. Yes. There are likely some 12 manuscripts that are missing and need to be updated on 13 there. 14 Q. Any on talc or ovarian cancer? 15 A. There are not. 16 Q. Okay. You're not a full professor. You weren't 17 a full professor in 2024 -- 2019. You're not a full 18 professor now; true? 19 A. I'm not. 20 Q. Okay. Are you still board certified in 21 pulmonary medicine?	1 website last week. I believe we're up to Exhibit 5; 2 right? 3 (Deposition Exhibit 5 was marked.) 4 BY MR. TISI: 5 Q. The website on Christian Merlo, M.D., transplant 6 pulmonology from the Johns Hopkins website. 7 Does that look like that -- to be true? 8 A. That's what it looks like it's from. 9 Q. All right. And it indicates that "Dr. Merlo is 10 an internist who specialists in pulmonary and critical 11 care medicine. Dr. Merlo has clinical expertise in the 12 care of patients with cystic fibrosis, as well as 13 clinical expertise in the care of patients with advanced 14 lung disease that may require" -- it actually gets cut 15 off here. 16 But that's true; right? 17 A. Yeah. Sure. That's true. 18 Q. So in looking at your current CV, 19 Exhibit Number -- I think it's 4? 20 MR. BISHOP: 4. 21

1 BY MR. TISI: 2 Q. You're still not published in the areas of talc; 3 true? 4 A. That's correct. 5 Q. Ovarian cancer? 6 A. That's correct. 7 Q. Epidemiology of ovarian cancer? 8 A. I do have a one transplant-related paper that 9 does look at the risk of malignancy after lung 10 transplantation, and ovarian cancer is one of the 11 malignancies that has been seen after that. 12 Q. Okay. Asbestos? 13 A. No. I have no papers on asbestos. 14 Q. Any papers on gynecology? 15 A. Not specifically. 16 Q. Any papers on contradictory data correction 17 methodology? 18 A. I -- I would have to understand a little bit 19 more about -- 20 Q. Have you ever published on the methods for doing 21 contradictory data correction? You know what that is;	Page 22 1 techniques as well. 2 Q. Have you written or published any articles using 3 sensitivity -- doing a sensitivity analysis related to 4 recall bias? 5 A. No. Not -- not that I can recall of. 6 Q. Now, we discussed -- now, as we discussed, you 7 wrote your original causation report in 2019. 8 Since 2019, have you ever submitted your report 9 or any portion of it for peer review in any way, your 10 litigation report? 11 A. Can you ask that again? 12 Q. Yes. 13 Have you ever submitted your litigation report 14 to be turned into a peer-reviewed paper? 15 A. No. I've never done that. 16 Q. Okay. Have you submitted your report to your 17 colleagues to ask them to take a look at your report and 18 see whether or not there are areas that you should 19 change? 20 A. I have not. 21 Q. Since 2019, have you submitted your report to
1 right? 2 A. So it depends. It depends on a lot of things. 3 I think if we're talking specifically about the O'Brien 4 paper where they did data correction and imputation, 5 yes. I have performed -- 6 Q. I didn't ask you that. 7 A. -- analysis on -- 8 Q. I asked you whether you published on it. 9 Whether you published on the methodology when 10 you use contradictory data correction -- 11 A. Yes, I have. I have performed imputation, which 12 is a form of -- 13 Q. Okay. 14 A. -- of working there contradictory data. 15 Q. And I've looked, and I saw one paper on that. 16 We'll talk about that later. It's a transplant paper; 17 is that true? 18 A. No. There are probably several. 19 Q. Okay. 20 A. I mean, there is one transplant paper but there 21 are some cystic fibrosis papers that use some imputation	Page 23 1 any professional organization for consideration like 2 NIH, FDA -- that's not a professional -- SGO or ACOG or 3 anything like that? 4 A. I have not. 5 Q. Have you submitted to the FDA? 6 A. I have not. 7 Q. Have you submitted to NIH? 8 A. I have not. 9 Q. So other than the lawyers in this case, nobody's 10 ever seen any systematic evaluation by you of the 11 relationship between talc and ovarian cancer as of 12 today; true? 13 A. That would be correct. Yes. 14 Q. And you've not submitted it to the EPA either; 15 true? 16 A. I have not. 17 Q. Now, as we sit here today, do you know that the 18 International Agency of Research on Cancer, or IARC, is 19 considering -- reconsidering the relationship between 20 talc and ovarian cancer? Do you know that? 21 A. So I've heard that. I don't know much about the

<p>1 specifics. But, yes. I have heard that.</p> <p>2 Q. Do you know that IARC actually requested that</p> <p>3 talc be reconsidered on a priority basis? Do you know</p> <p>4 that to be true?</p> <p>5 MR. BISHOP: Objection to the form. Vague.</p> <p>6 Foundation.</p> <p>7 THE WITNESS: I'm not aware of that. I'm not</p> <p>8 part of IARC, so I'm not aware of the requests and</p> <p>9 things like that.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Well, do you know that IARC actually reached out</p> <p>12 to the epidemiology world and the toxicology world</p> <p>13 and -- to see whether anybody would apply to sit on any</p> <p>14 of their panels to review the evidence of the</p> <p>15 relationship between talc and ovarian cancer?</p> <p>16 A. I'm not aware of that.</p> <p>17 Q. Okay. I'm going to show you what I'd like to</p> <p>18 have marked as Exhibit Number 6.</p> <p>19 (Deposition Exhibit 6 was marked.)</p> <p>20 BY MR. TISI:</p> <p>21 Q. Do you know what I put in front of you?</p>	<p>Page 26</p> <p>1 Q. Okay. Now, you look at Exhibit Number 2, which</p> <p>2 is your expert report in the MDL case, there's a</p> <p>3 conclusion section on page 73 entitled "Summaries and</p> <p>4 Conclusions."</p> <p>5 Do you see that?</p> <p>6 A. I do, yes.</p> <p>7 Q. Okay. And I have actually pulled out that page.</p> <p>8 I'd like to have it marked as Exhibit Number 7. My</p> <p>9 colleague here is keeping track of my exhibits, so</p> <p>10 I appreciate her very much. Here is Exhibit Number 7.</p> <p>11 (Deposition Exhibit 7 was marked.)</p> <p>12 BY MR. TISI:</p> <p>13 Q. Does that look like that's the page of the</p> <p>14 summary conclusion section from 2024?</p> <p>15 MR. TISI: And for the record, I wrote "2024" on</p> <p>16 the top and circled some paragraphs.</p> <p>17 THE WITNESS: That's correct.</p> <p>18 BY MR. TISI:</p> <p>19 Q. All right. And I did the same thing if you look</p> <p>20 at -- I did the same thing -- and I will represent to</p> <p>21 you I just didn't bring it. I pulled the same page on</p>
<p>1 A. I do, yes.</p> <p>2 Q. Okay. This is April 2024, about the time you</p> <p>3 were actually drafting your expert report in this case;</p> <p>4 right?</p> <p>5 A. I was in the process of updating it. Yes.</p> <p>6 Q. Okay. And there's actually a call for data.</p> <p>7 Do you see that on the right-hand side by the</p> <p>8 IARC committee?</p> <p>9 A. I do see "call for data." Yes.</p> <p>10 Q. Okay. And one of the -- in the meeting, it</p> <p>11 talks about talc and -- I don't know how to pronounce</p> <p>12 the second word.</p> <p>13 But you see that there's a meeting request for</p> <p>14 data relating to, among other things, talc?</p> <p>15 A. I do. It says that there's a call for data, and</p> <p>16 then there's a call for experts, which is -- which was</p> <p>17 closed on the 31st of July, 2023.</p> <p>18 Q. All right. My question was: Did you ever apply</p> <p>19 to IARC or submit data for them to consider your</p> <p>20 opinions?</p> <p>21 A. No.</p>	<p>Page 27</p> <p>1 page 46 of your 2019 report, which I'd like to have</p> <p>2 marked as number 8.</p> <p>3 (Deposition Exhibit 8 was marked.)</p> <p>4 BY MR. TISI:</p> <p>5 Q. There's a section entitled "Summary and</p> <p>6 Conclusions," assessing causality. And I'm going to ask</p> <p>7 you to accept my representation that I didn't change any</p> <p>8 of the words or anything like that and I did the same</p> <p>9 thing.</p> <p>10 A. That's correct.</p> <p>11 Q. All right. So your -- just to kind of round</p> <p>12 this out, both of -- in both of them, I've actually</p> <p>13 circled your methodology criticisms, generally speaking,</p> <p>14 and your conclusions about plaintiffs' experts using --</p> <p>15 with their methodology and the problems, generally</p> <p>16 speaking, that you had with the methodology that they</p> <p>17 employed; is that correct?</p> <p>18 A. That is correct. Yes.</p> <p>19 Q. All right. And will you agree that other than a</p> <p>20 few stylistic changes -- and feel free to look at</p> <p>21 them -- they're exactly the same?</p>

<p style="text-align: right;">Page 30</p> <p>1 A. Yeah. They're exactly the same because my      2 opinion hasn't changed based on the methodology of the      3 plaintiffs' experts.</p> <p>4 Q. Right. That's my point is the methodology      5 employed by plaintiffs' experts has not, in your view,      6 changed in any -- in any fashion. You still considered      7 it flawed. You still considered it inappropriate. But      8 it hasn't changed from your report in 2019 to your      9 report in 2024. The only thing that's changed is      10 there's some additional data?</p> <p>11 MR. BISHOP: Object to the form.</p> <p>12 BY MR. TISI:</p> <p>13 Q. True?</p> <p>14 MR. BISHOP: I'm sorry. Object to form.</p> <p>15 Compound.</p> <p>16 THE WITNESS: My opinion regarding the flawed      17 methodology of plaintiffs' experts has not changed.</p> <p>18 What has changed in my report has been the      19 addition of a few more studies to -- to add to my      20 opinion.</p> <p>21</p>	<p style="text-align: right;">Page 32</p> <p>1 A. That's correct.</p> <p>2 Q. All right. And just like -- similarly, in 2024,      3 you say methodologically plaintiffs' experts play      4 particular attention to criticizing cohort studies with      5 little acknowledgement to the limitations of case      6 control studies that find weak associations; correct?</p> <p>7 A. That's correct.</p> <p>8 Q. All right. You said that in 2019. You still      9 believe it's true in 2024; true?</p> <p>10 A. That's still my opinion. Yes.</p> <p>11 Q. Okay. You say in 2024, "Plaintiffs' experts      12 generally agree that even the studies that do show an      13 association between cosmetic talc and ovarian cancer      14 have found a relative risk of 1.2 to 1.6. This, by      15 definition, is weak association. Plaintiffs nonetheless      16 attempt to characterize the association as strong";      17 correct?</p> <p>18 A. That is correct.</p> <p>19 Q. And that's the very same opinion you had in      20 2019; correct?</p> <p>21 A. Yeah. I think if I could change one thing in</p>
<p style="text-align: right;">Page 31</p> <p>1 BY MR. TISI:</p> <p>2 Q. Right. And we'll talk about that. But I'm      3 really trying to tease out the difference between      4 methodology and the application of the methodology to      5 the data that currently exists.</p> <p>6 The methodology you employed and the methodology      7 that they employed is the same as it was in 2019. It's      8 just we have new data?</p> <p>9 A. In general --</p> <p>10 MR. BISHOP: I'm sorry. Objection. Asked and      11 answered.</p> <p>12 Go ahead.</p> <p>13 THE WITNESS: In general, yes.</p> <p>14 BY MR. TISI:</p> <p>15 Q. All right. So, for example, in 2019, you say      16 that -- I'm sorry. Your 2024 report, you say that      17 plaintiffs ignore the hierarchy of evidence evaluating      18 studies and rely on study designs that are inherently      19 susceptible to bias.</p> <p>20 That was the same opinion you had in 2019;      21 correct?</p>	<p style="text-align: right;">Page 33</p> <p>1 that, I would change the 1.2 to 1.8, given the most      2 recent study. I may have just overlooked that part of      3 it.</p> <p>4 Q. Okay. You say, "Likewise, plaintiffs' experts      5 try to demonstrate a dose response relationship by      6 relying on methodologically flawed studies and      7 statistically insignificant trend lines."</p> <p>8 That's exactly what you said you said in 2019,      9 and you still believe it to be true in 2024?</p> <p>10 A. That's correct.</p> <p>11 Q. They also claim to seek consistency where the      12 studies are inherently inconsistent.</p> <p>13 That was your opinion in 2019. It's still your      14 opinion in 2024?</p> <p>15 A. That's correct.</p> <p>16 Q. Okay. Now, setting aside the interpretation of      17 the new evidence and studies like the post-2019 O'Brien      18 studies, which we will discuss, can you think of any      19 additional generally methodologic flaw or principle that      20 plaintiffs' experts failed to follow other than those      21 that you generally outlined in your original 2019</p>

<p>1 report?</p> <p>2 A. So my opinion has not changed. And that talks</p> <p>3 about inconsistency. That talks about the potential for</p> <p>4 bias. That talks about the -- the -- the disagreement</p> <p>5 in the strength of association.</p> <p>6 So I think those -- those opinions, in general,</p> <p>7 have not changed.</p> <p>8 Q. Okay. But -- so, I mean, again, I'm trying to</p> <p>9 get you here: Putting aside plaintiffs' experts'</p> <p>10 interpretations of new studies after 2019, can you think</p> <p>11 of any additional methodologic principle or method that</p> <p>12 plaintiffs' experts failed to apply when assessing the</p> <p>13 literature that is not captured in your criticisms from</p> <p>14 2019?</p> <p>15 MR. BISHOP: Object to the form. 2024 report</p> <p>16 stands on its own.</p> <p>17 THE WITNESS: I think it's contained in my 2024</p> <p>18 report.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Right.</p> <p>21 And in terms of methodology, there's no</p>	<p>Page 34</p> <p>1 say -- I'm going to ask you to look at it here.</p> <p>2 (Deposition Exhibit 9 was marked.)</p> <p>3 BY MR. TISI:</p> <p>4 Q. And I'm sorry I'm asking you to stand up.</p> <p>5 I don't --</p> <p>6 A. No. That's okay.</p> <p>7 Q. I don't mean to do that.</p> <p>8 A. Good exercise.</p> <p>9 Q. It's just I really don't want to trip over the</p> <p>10 court reporter here.</p> <p>11 So number 9 are quotes from the different -- on</p> <p>12 the different criticisms that you had of plaintiffs'</p> <p>13 experts from the Daubert order. And feel free to take a</p> <p>14 look at that. And I just want to see if the defense and</p> <p>15 the judge actually characterized yours and other J&amp;J</p> <p>16 witnesses' methodologic criticisms correctly.</p> <p>17 So if you take a look at that and we can --</p> <p>18 A. Sure. Okay. What was the question again? I'm</p> <p>19 sorry.</p> <p>20 Q. Yeah. There was no question. I'm going to ask</p> <p>21 you.</p>
<p>1 difference?</p> <p>2 A. That's my opinion. Yes.</p> <p>3 Q. Okay. All right. Do you know what Daubert is?</p> <p>4 A. Not -- you'd have to explain that to me. But --</p> <p>5 Q. Well, you know generally the question -- you</p> <p>6 actually -- I think your original report was entitled</p> <p>7 "Expert on General Causation for Daubert," if I remember</p> <p>8 correctly; correct?</p> <p>9 A. That's correct.</p> <p>10 Q. All right. So you had a general understanding</p> <p>11 that in Daubert, the Court was to test the methodology</p> <p>12 of different experts and see whether they applied an</p> <p>13 appropriate scientific methodology.</p> <p>14 Do you remember that?</p> <p>15 A. That sounds about right.</p> <p>16 Q. All right. Now, do you know that the court held</p> <p>17 a hearing on methodology in the federal MDL case?</p> <p>18 You're aware of that; right?</p> <p>19 A. Very vaguely. Yes.</p> <p>20 Q. And I'm going to hand to you Exhibit Number 9,</p> <p>21 which I will say that I created. And so I'm going to</p>	<p>Page 35</p> <p>1 Having read that, did the judge, as</p> <p>2 characterizing what the defendants, J&amp;J, claimed here</p> <p>3 actually -- accurately capture your criticisms of the</p> <p>4 plaintiffs' experts?</p> <p>5 MR. BISHOP: Objection. Overbroad and compound.</p> <p>6 THE WITNESS: Can you ask that again?</p> <p>7 BY MR. TISI:</p> <p>8 Q. Yeah.</p> <p>9 Did the judge understand the criticisms that</p> <p>10 you -- that you and J&amp;J's lawyers leveled against</p> <p>11 plaintiffs' experts, as expressed in your 2019 report?</p> <p>12 MR. BISHOP: Objection. Same -- same</p> <p>13 objections, plus calls for speculation. And it's only</p> <p>14 excerpts from the order.</p> <p>15 MR. TISI: I understand.</p> <p>16 THE WITNESS: So this piece of paper has three</p> <p>17 titles on it: strength of association, consistency, and</p> <p>18 dose response. They're -- these appear to be, but</p> <p>19 I would only be guessing, that they're a summary of what</p> <p>20 you're telling me the judge said about these different</p> <p>21 parts of a Bradford Hill framework.</p>

Page 38	Page 40
1 BY MR. TISI:	1 MR. BISHOP: I presume you mean 2019?
2 Q. Well, it's not what the judge said. I didn't	2 MR. TISI: 2019.
3 give you the judge's analysis. I gave you how the	3 MR. BISHOP: Okay. You said 2012.
4 defendants characterized their arguments regarding	4 MR. TISI: I'm sorry.
5 methodology.	5 BY MR. TISI:
6 For example, defendants submit there is a	6 Q. Are you aware that your causation report and
7 hierarchy of evidence of epidemiologic study, which	7 your opinions on methodology were actually sent to you
8 include a descending order of reliability --	8 and considered by independent scientists by
9 COURT REPORTER: Slow down.	9 Johnson & Johnson?
10 BY MR. TISI:	10 A. Can you ask that again?
11 Q. Descending order of reliability, cohort studies,	11 Q. Yeah.
12 case control studies, and cross-sectional studies.	12 Are you aware that your causation report from
13 Those are the kinds of criticisms that you made;	13 2019 and your opinions about the methodology employed by
14 correct?	14 you was actually reviewed by independent scientists and
15 A. Maybe I'm misunderstanding who wrote this.	15 regulators?
16 Q. This is the judge writing -- writing what she	16 MR. BISHOP: Object to form.
17 understood the defendants' arguments to be.	17 THE WITNESS: I'm not aware of that.
18 A. Got it.	18 MR. BISHOP: I'm sorry. Vague. Foundation.
19 Q. Okay. So did the judge accurately understand	19 BY MR. TISI:
20 what the defendants' arguments are, at least as far as	20 Q. Prior to your 2019 deposition, you recall that
21 you're concerned?	21 I asked you about a draft assessment from Health Canada
Page 39	Page 41
1 MR. BISHOP: Object to the form. That calls for	1 from 2019. Do you remember that? And you said you
2 speculation. It's overbroad to the extreme.	2 weren't aware of that.
3 THE WITNESS: It's impossible for me to say	3 A. I vaguely remember that question. That was a
4 that, because the strength of association -- there are	4 long time ago.
5 other factors that are -- that would be factored into	5 Q. Do you know that subsequent to 2019, from
6 the strength of association --	6 your -- after your deposition, J&J provided your expert
7 BY MR. TISI:	7 report to Health Canada for consideration as part of a
8 Q. Okay.	8 comment period for their regulatory findings?
9 A. -- not just the hierarchy of observation of	9 MR. BISHOP: Objection. Vague. Overbroad. No
10 epidemiologic studies.	10 foundation.
11 There's no talk about -- about what a point	11 THE WITNESS: I'm not --
12 estimate would be or what a strong point estimate would	12 MR. BISHOP: Calls for speculation.
13 be, what a weak point estimate would be.	13 THE WITNESS: I'm not aware of that.
14 Q. Okay.	14 BY MR. TISI:
15 A. So that's -- it's impossible for me to say what	15 Q. Okay. And do you know that -- I noticed that --
16 this person was thinking.	16 well, as part of your reliance materials, you saw a --
17 Q. Okay. Okay. All right. I think the record	17 there was a big, thick document that was -- J&J had
18 will speak for itself.	18 actually compiled in response to Health Canada.
19 All right. Let's switch topics a bit to discuss	19 Do you remember that?
20 your methodology, since 2012, what you've done.	20 A. Vaguely remember that.
21 Are you aware --	21 Q. Okay. And you understand -- do you have any

1 understanding, in addition to its own analysis, it 2 provided with the -- it provided access to Health 3 Canada, the expert reports filed in the MDL? Are you 4 aware of that? 5 MR. BISHOP: Objection. Asked and answered. 6 THE WITNESS: Can you ask that again? 7 BY MR. TISI: 8 Q. Yeah. 9 A. I didn't understand. 10 Q. You're aware in addition to your own evaluation, 11 they provided expert reports like Dr. Diette and 12 Dr. Merlo and Dr. McTiernan and Dr. Siemiatycki, 13 provided those all for consideration by Health Canada? 14 MR. BISHOP: Objection. Foundation. Also 15 compound. 16 THE WITNESS: I -- I don't know what J&J 17 provided to Health Canada -- 18 BY MR. TISI: 19 Q. Okay. 20 A. -- in whatever they were asking for 21 consideration.	Page 42 1 Did J&J tell you that Health Canada actually 2 considered your opinions in reviewing the evidence as 3 part of putting together their final report on the issue 4 of causation and talc and ovarian cancer? Did it tell 5 you that? 6 A. I'm -- 7 MR. BISHOP: I'm sorry. Objection. Foundation. 8 Calls for speculation. 9 THE WITNESS: Again, I'm not aware of J&J -- 10 BY MR. TISI: 11 Q. Okay. 12 A. -- doing that. 13 Q. In fact, J&J even as of today, other than their 14 lawyers, have never asked you to do anything with 15 respect to any professional epidemiology work or 16 pulmonary work or critical care work or anything. 17 You've never consulted with them in the normal course of 18 business, have you? 19 A. The only thing that I was asked to do was to 20 provide an opinion based on the epidemiologic medical 21 literature to provide an opinion whether or not cosmetic
Page 43 1 Q. I'm going to show you what I have marked as 2 Exhibit Number 10. 3 (Deposition Exhibit 10 was marked.) 4 BY MR. TISI: 5 Q. Have you seen the final report by Health Canada 6 that was published in 2021? 7 A. I have not. 8 Q. J&J did not provide you with their -- the 9 regulatory authority's review of the scientific 10 evidence, including your own expert report? 11 MR. BISHOP: Object to the form. 12 THE WITNESS: So -- 13 MR. BISHOP: Compound. Calls for speculation. 14 THE WITNESS: -- what I was asked to provide was 15 my opinion based on the peer-reviewed epidemiologic 16 literature. And this Health Canada report, which I have 17 not read, would not be part of the peer-reviewed 18 published literature. 19 BY MR. TISI: 20 Q. Well, that's really not my question, so let me 21 rephrase the question.	Page 45 1 talc has a causal association with ovarian cancer. 2 Q. In litigation? 3 A. In litigation, yes. 4 Q. Okay. Putting aside your litigation report, 5 have you ever -- has J&J ever reached out to you, even 6 as of today, and said, "We really need your expertise on 7 the wide variety of drugs and products that we've 8 produced because we need your expertise in any aspect of 9 your training and experience"? Epidemiology, pulmonary 10 medicine, anything? 11 A. J&J has not reached out directly to me. 12 Q. So the only thing that they ever reached out to 13 you to do was to do a litigation report; correct? 14 A. I don't specifically recall who reached out to 15 me in the beginning about this. 16 Q. Okay. 17 A. But someone did. 18 Q. Their lawyers? 19 A. Likely, yes. 20 Q. Yeah. 21 J&J itself has never reached out to you for any

12 (Pages 42 - 45)

<p style="text-align: right;">Page 46</p> <p>1 professional advice or work; true?</p> <p>2 MR. BISHOP: Objection. Asked and answered.</p> <p>3 THE WITNESS: That's correct.</p> <p>4 BY MR. TISI:</p> <p>5 Q. All right. Now, did they tell you, though, that</p> <p>6 as part of the normal course of business, they submitted</p> <p>7 your litigation report to the Canadian authorities?</p> <p>8 MR. BISHOP: Objection. Asked and answered.</p> <p>9 THE WITNESS: Yeah, I thought I answered that</p> <p>10 already.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. And the answer was no, you did not know</p> <p>13 that?</p> <p>14 A. That's correct.</p> <p>15 Q. And they never told you that they -- that they</p> <p>16 considered your report, Dr. Diette's report,</p> <p>17 Dr. McTiernan's report, Dr. Singh's report,</p> <p>18 Dr. Smith-Bindman's report, and all the expert reports</p> <p>19 that were available at the time, and yet they still</p> <p>20 found that talc was a likely cause of ovarian cancer.</p> <p>21 They didn't tell you that, did they?</p>	<p style="text-align: right;">Page 48</p> <p>1 BY MR. TISI:</p> <p>2 Q. Well, if you will take a look at the document</p> <p>3 I put in front of you, on page 55, for example, there's</p> <p>4 a list of things that they considered.</p> <p>5 Do you see near the bottom, expert report of</p> <p>6 Christian Merlo, expert report of Anne McTiernan?</p> <p>7 Do you see that?</p> <p>8 A. I do see that. Yes.</p> <p>9 Q. Okay. And do you also see, if you go to page --</p> <p>10 page 2 of the report, it says that their report was</p> <p>11 actually peer reviewed?</p> <p>12 Do you see that?</p> <p>13 I'll read it to you. It says, "Additionally,</p> <p>14 the draft screening assessment was subject to a 60-day</p> <p>15 public comment period. Additional information was</p> <p>16 submitted during the public period, which was reviewed</p> <p>17 and considered in the final screening assessment."</p> <p>18 And if you go to the sentence before, it says,</p> <p>19 "The human health portion of this assessment had</p> <p>20 undergone external peer review."</p> <p>21 Do you see that?</p>
<p style="text-align: right;">Page 47</p> <p>1 MR. BISHOP: Objection. Foundation. Overbroad.</p> <p>2 Calls for speculation.</p> <p>3 THE WITNESS: Can you ask that again? It was a</p> <p>4 complicated question.</p> <p>5 MR. TISI: Yeah. Why don't you read it again,</p> <p>6 please?</p> <p>7 BY MR. TISI:</p> <p>8 Q. I'll ask the question again.</p> <p>9 They didn't tell you that they had submitted --</p> <p>10 just like they submitted to Judge Wolfson in the federal</p> <p>11 MDL proceedings they submitted to Health Canada the</p> <p>12 reports that were filed in the MDL in 2019, your report,</p> <p>13 Dr. Diette's report, Dr. Smith-Bindman's report,</p> <p>14 Dr. McTiernan's report, Dr. Siemiatycki's report. They</p> <p>15 were all submitted to Health Canada.</p> <p>16 Did you know that?</p> <p>17 MR. BISHOP: Objection. Foundation. Calls for</p> <p>18 speculation. Overbroad.</p> <p>19 THE WITNESS: I think I answered that already.</p> <p>20 I'm not aware of what J&amp;J -- if they submitted anything</p> <p>21 to Health Canada.</p>	<p style="text-align: right;">Page 49</p> <p>1 A. I don't see that second part.</p> <p>2 Q. Go up above -- mid-sentence -- beginning -- it</p> <p>3 says -- right here.</p> <p>4 A. Yeah. I see where it says, "The human health</p> <p>5 portion of this assessment has undergone external peer</p> <p>6 review."</p> <p>7 They don't describe that external peer review.</p> <p>8 And they also say, "While external comments were taken</p> <p>9 into consideration, the final content and outcome of the</p> <p>10 screening assessment remain the responsibility of Health</p> <p>11 Canada and Environmental and Climate Change Canada."</p> <p>12 So, I mean, yes. There's a -- there was a draft</p> <p>13 that was subject to a 60-day public comment period, but</p> <p>14 that's not exactly what would happen in a peer-reviewed</p> <p>15 manuscript.</p> <p>16 Q. Go to page 31 -- and I'm just going to use by</p> <p>17 way of example. So if you look at page 31 -- and it</p> <p>18 comes under the section of "Consistency," if you look at</p> <p>19 the second -- the page before on page 30.</p> <p>20 Do you see that?</p> <p>21 A. I do, yes.</p>

13 (Pages 46 - 49)

<p style="text-align: right;">Page 50</p> <p>1 Q. Okay. And they actually cite you and the      2 experts in the case. It says, for example -- in the      3 middle of the first full paragraph, it says, "Specific      4 to talc and ovarian cancer, some recently analyses have      5 given precedence to the results of cohort studies,      6 arguing they provide stronger evidence of an association      7 in case controls."</p> <p>8 And it cites, among other things,      9 Johnson &amp; Johnson?</p> <p>10 Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. Okay. And then it says, "Other analyses support      13 the view that such generalizations cannot be made, and      14 there are many factors affecting the validity of the      15 studies regardless of design."</p> <p>16 And they cite plaintiffs' experts' scientific      17 reports.</p> <p>18 Do you see that?</p> <p>19 A. I do, yes.</p> <p>20 Q. Okay. In the next sentence, it says, "The      21 available cohort studies did not demonstrate the same</p>	<p style="text-align: right;">Page 52</p> <p>1 BY MR. TISI:      2 Q. All right. And so J&amp;J provided you with a lot      3 of information about comprehensive reviews that were      4 done in this case, but they never provided you with what      5 Health Canada did, did they?</p> <p>6 MR. BISHOP: Object to form. Compound.</p> <p>7 THE WITNESS: Again, I'm going to go back to the      8 reason that I was asked to perform my analysis, and that      9 was to use the peer-reviewed published literature.</p> <p>10 BY MR. TISI:      11 Q. Okay.      12 A. And this would not be included in that.      13 Q. Okay. Now, let's talk about -- you made some --      14 you had some opinions, for example, on the PDQ.      15 Do you remember that? In your report.      16 A. I did reference a recent update to the PDQ.      17 Yes.      18 Q. And, actually, in your original report, you      19 referred to the PDQ; right?      20 A. I believe so. I think the update -- I did an      21 update based on when I accessed the website. Yes.</p>
<p style="text-align: right;">Page 51</p> <p>1 level of statistical significance in the case control      2 studies."</p> <p>3 And, actually, it continues on and cites you and      4 Dr. Diette?</p> <p>5 Do you see that?</p> <p>6 A. I do, yes.</p> <p>7 Q. And in the end of the day, if you look at the --      8 if you look at the conclusion -- go to page 45. The end      9 of the paragraph at the top of the page, it says --      10 citing you, among other things, it then goes on to say,      11 "While there may not be consensus within the scientific      12 community regarding the interpretation of the      13 epidemiologic information, after weighing the available      14 lines of evidence, the assessment determined that      15 current data is indicative of causal effect."</p> <p>16 Do you see that?</p> <p>17 MR. BISHOP: This -- I'm sorry. This document      18 speaks for itself, and it's a document that this witness      19 is not familiar with.</p> <p>20 MR. TISI: Understood.</p> <p>21 THE WITNESS: I do read that. Yes.</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. All right. To your knowledge, is PDQ a      2 peer-reviewed, published literature?</p> <p>3 A. I'm not aware of what -- what goes into who      4 publishes the PDQ on the website. That, actually,      5 paragraph in my report would not change my opinion --</p> <p>6 Q. Didn't ask that.</p> <p>7 A. -- either way.</p> <p>8 Q. You said you only considered -- if I'm      9 understanding you correctly, you only considered the      10 published, peer-reviewed literature. And you actually      11 referred to, among other things, the PDQ.</p> <p>12 And you -- that's not published or peer      13 reviewed, is it?</p> <p>14 A. I don't know if it is or not.</p> <p>15 Q. Okay. Let's talk about -- I'm going to switch      16 topics a bit.</p> <p>17 You've been working on talc litigation with J&amp;J      18 lawyers for at least six years; correct?</p> <p>19 A. I believe either 2018, 2019, I was asked to      20 provide -- to look at the literature and to provide an      21 opinion.</p>

14 (Pages 50 - 53)

<p style="text-align: right;">Page 54</p> <p>1 Q. Okay. And you've actually testified as an 2 expert in two cases, to the best of my knowledge; 3 correct?</p> <p>4 A case in Georgia and -- actually, two cases in 5 Georgia.</p> <p>6 A. Two cases in Georgia and with you. So three 7 depositions prior to this.</p> <p>8 Q. Oh, did you testify at trial?</p> <p>9 A. No.</p> <p>10 Q. Okay. The two cases in Georgia, were they 11 mesothelioma cases? Were they ovarian cancer?</p> <p>12 A. Ovarian cancer.</p> <p>13 Q. Okay. And how much money do you -- have you 14 made over the past six years testifying on behalf of J&amp;J 15 in connection with your work with J&amp;J lawyers?</p> <p>16 A. So --</p> <p>17 Q. Total.</p> <p>18 A. Yeah. I want to step back. I'm not testifying 19 for J&amp;J. I'm testifying for my opinion based on the 20 medical literature and my opinion on whether or not 21 cosmetic talc is causal in the relationship with ovarian</p>	<p style="text-align: right;">Page 56</p> <p>1 A. Yes.</p> <p>2 Q. So that would be a total -- you know, putting 3 the pandemic in there -- is how much?</p> <p>4 A. Well, in between 5- and \$600,000 --</p> <p>5 Q. Okay.</p> <p>6 A. -- would be my estimate.</p> <p>7 Q. I'm going to have marked --</p> <p>8 I'm going to have marked -- actually, I'm going 9 to mark these at the end because I want to take these in 10 order.</p> <p>11 But you did provide us with bills; correct?</p> <p>12 A. Invoices. Yes.</p> <p>13 Q. Invoices.</p> <p>14 And we talked about VeraMedica last time.</p> <p>15 They're an outside organization that helps you collect 16 documents and do administerial things; correct?</p> <p>17 A. Yes. They help with administrative things.</p> <p>18 Q. I notice from the fee schedule you have that 19 they have an epidemiologist and on-board nurse, 20 et cetera.</p> <p>21 Did you use any of them in any way in connection</p>
<p style="text-align: right;">Page 55</p> <p>1 cancer.</p> <p>2 Q. Okay. I get it. I get it. But they're paying 3 you for that testimony; correct?</p> <p>4 MR. BISHOP: Object to form. Mischaracterizes.</p> <p>5 BY MR. TISI:</p> <p>6 Q. They've paid you for the work that you've done 7 in this case; true?</p> <p>8 A. They're paying for my opinion. Yes.</p> <p>9 Q. Right. All right.</p> <p>10 Now, you have -- the work that you've done over 11 the past six years, how much would you say that you've 12 made from J&amp;J in terms of money?</p> <p>13 A. Sure. I -- there was a pause during -- during 14 the pandemic.</p> <p>15 Q. Um-hum.</p> <p>16 A. But I think, in general -- although I would be 17 guessing, but I'm going to give my best estimate.</p> <p>18 Q. Please.</p> <p>19 A. I would say between in between 100- and \$200,000 20 a year.</p> <p>21 Q. 100- and \$200,000 a year?</p>	<p style="text-align: right;">Page 57</p> <p>1 with your report?</p> <p>2 A. I mean, my report is based on the time that 3 I spent reviewing the medical literature and -- and 4 writing.</p> <p>5 Q. Okay.</p> <p>6 A. All those other things, I don't know what those 7 are.</p> <p>8 Q. Okay. So you don't know what they did and what 9 they did not do in connection with your report?</p> <p>10 A. I don't. I know that some people printed things 11 out for me and made binders, but what that costs or what 12 that --</p> <p>13 Q. No --</p> <p>14 A. I don't --</p> <p>15 Q. What I'm asking you for, Doctor, is a different 16 question.</p> <p>17 My question is: Did they do any substantive 18 work? For example, helping you calculate odds ratios or 19 help you figure out things about multiple imputation or 20 anything like that.</p> <p>21 Did they do anything technical with your</p>

<p>1 reports?</p> <p>2 A. No.</p> <p>3 Q. Okay. I'm going to mark this.</p> <p>4 MR. TISI: Remind me to mark this at the end.</p> <p>5 BY MR. TISI:</p> <p>6 Q. You know, I see bills here in the range of</p> <p>7 \$237,000. But as I think you said, over time, it's</p> <p>8 closer to 5-, \$600,000; is that right?</p> <p>9 A. That would be my best estimate based on the</p> <p>10 number of years and what it would be for -- per year.</p> <p>11 Again, there was a pause during COVID.</p> <p>12 Q. Okay.</p> <p>13 A. So it could be an overestimate.</p> <p>14 Q. Now I'm going to hand you Exhibit Number 9 [sic],</p> <p>15 which is the notice of deposition.</p> <p>16 I'm going to hand you -- have you had an</p> <p>17 opportunity to look at the notice of deposition that was</p> <p>18 filed in this case?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And we're at number 11; right?</p> <p>21 MR. BISHOP: That's correct.</p>	<p>Page 58</p> <p>1 cancer.</p> <p>2 Do you see that?</p> <p>3 A. I do, yes.</p> <p>4 Q. Have you reached out in any way to any authors</p> <p>5 of any of the published studies that are at issue in</p> <p>6 this case, including the O'Brien authors?</p> <p>7 A. I have not.</p> <p>8 Q. Have you reached out or spoken to anybody who</p> <p>9 publishes the PDQ?</p> <p>10 A. I have not.</p> <p>11 Q. Have you ever spoken -- you know who Dr. Diette</p> <p>12 is; correct?</p> <p>13 A. Yes.</p> <p>14 Q. Have you ever spoken to Dr. Diette about your</p> <p>15 opinions in this case?</p> <p>16 A. I don't specifically recall speaking about my</p> <p>17 opinions, but I'm sure that we have discussed aspects</p> <p>18 in, you know -- from time to time.</p> <p>19 Q. Have you spoken to any of your other colleagues</p> <p>20 other than the other litigation expert in this case?</p> <p>21 Any of your other epidemiology colleagues who are not</p>
<p>1 (Deposition Exhibit 11 was marked.)</p> <p>2 THE WITNESS: Thanks.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Have you looked at -- have you looked at this in</p> <p>5 order to try and comply with Exhibit Number 11?</p> <p>6 A. And this is Exhibit 11, documents reflecting</p> <p>7 requests by you or offers to you --</p> <p>8 Q. Yes.</p> <p>9 A. -- of funding to study talcum powder products?</p> <p>10 Q. No.</p> <p>11 I'm just asking you: Have you seen this</p> <p>12 document and looked through it?</p> <p>13 A. Oh. I have -- Yes. I have looked through it.</p> <p>14 Yes.</p> <p>15 Q. I'm going to ask you to look -- go to number 14.</p> <p>16 It says documents relating to communications</p> <p>17 between you and certain entities.</p> <p>18 Do you see that?</p> <p>19 A. I do, yes.</p> <p>20 Q. Exhibit A is authors of any published study</p> <p>21 concerning talcum powder product and talc and ovarian</p>	<p>Page 59</p> <p>1 participating in this case about your opinions?</p> <p>2 A. I have not.</p> <p>3 Q. Okay. So the only person at Hopkins you</p> <p>4 actually spoke to is the other litigation guy?</p> <p>5 A. Well, his office is right next to mine and we</p> <p>6 are friends. And from time to time, things may --</p> <p>7 things may come up.</p> <p>8 Q. I'm sure you are -- you have other people who</p> <p>9 have offices near you as well; right?</p> <p>10 A. There are. But, you know, his -- he -- I've</p> <p>11 known him for a long time, and we are closer colleagues</p> <p>12 than maybe some others who are in close proximity.</p> <p>13 Q. And you are co-experts for J&amp;J in the talcum</p> <p>14 powder litigation; correct?</p> <p>15 A. So we are co-experts. Yes, we are.</p> <p>16 Q. Okay.</p> <p>17 (Recess taken.)</p> <p>18 (Brandy Harris, Esq. and David Dearing, Esq.</p> <p>19 joined via Zoom.)</p> <p>20 BY MR. TISI:</p> <p>21 Q. Couple questions about that. You say your</p>

<p style="text-align: right;">Page 62</p> <p>1 office is right next to Dr. Diette's.</p> <p>2 Did you collaborate in any fashion on your</p> <p>3 supplemental 2024 reports in terms of communicating</p> <p>4 ideas back and forth, for example, about the O'Brien</p> <p>5 2024 study?</p> <p>6 A. Not that I recall.</p> <p>7 Q. Okay. Have you emailed each other about the</p> <p>8 specifics about the talc litigation?</p> <p>9 A. We have not.</p> <p>10 Q. On page 34 of your expert report, your MDL</p> <p>11 expert report, you make the statement that you had a</p> <p>12 concern that the authors had manipulated data in order</p> <p>13 to demonstrate a predetermined result.</p> <p>14 Do you remember that phrase?</p> <p>15 A. I do. But if you could point me to that --</p> <p>16 Q. Yeah.</p> <p>17 A. -- that sentence, that would be great.</p> <p>18 Q. Yeah. On page 34, right before meta-analysis,</p> <p>19 it says, "Given that this model is fundamentally based</p> <p>20 on the imputation of missing data, it raises concern for</p> <p>21 the data manipulation in order to demonstrate a</p>	<p style="text-align: right;">Page 64</p> <p>1 BY MR. TISI:</p> <p>2 Q. Okay. What did you do to investigate that</p> <p>3 concern?</p> <p>4 A. I looked at the data --</p> <p>5 Q. Did you contact --</p> <p>6 A. -- itself.</p> <p>7 Q. Did you contact anybody?</p> <p>8 A. I wasn't a peer reviewer on that manuscript.</p> <p>9 Had I been, I would have raised that concern.</p> <p>10 Q. Did you -- you know that's there a corresponding</p> <p>11 author on the study; correct? Dr. O'Brien.</p> <p>12 A. That's correct.</p> <p>13 Q. Did you ever contact Dr. O'Brien and say,</p> <p>14 "Dr. O'Brien, you know, I have some concerns here that</p> <p>15 maybe you were manipulating data"?</p> <p>16 Did you ever do that?</p> <p>17 A. Well, they actually did manipulate data.</p> <p>18 Q. I'm not -- to --</p> <p>19 A. And so --</p> <p>20 Q. Let me rephrase the question. I'm withdrawing</p> <p>21 the question. I'm going to --</p>
<p style="text-align: right;">Page 63</p> <p>1 predetermined result."</p> <p>2 Did I read that correctly?</p> <p>3 A. You did, yes.</p> <p>4 Q. So you had a concern about that.</p> <p>5 Did you have any documents or anything that</p> <p>6 would support that concern or anything about that?</p> <p>7 A. Other than the way in which this study was</p> <p>8 performed --</p> <p>9 Q. Right. So you have -- I'm sorry. I didn't mean</p> <p>10 to interrupt you.</p> <p>11 So you have no evidence or documents that would</p> <p>12 suggest that the authors manipulated data in order to</p> <p>13 get a predetermined result?</p> <p>14 A. Other than the manuscript itself, yes.</p> <p>15 Q. Okay. So you think that the manuscript that</p> <p>16 passed peer review demonstrates that it was done for a</p> <p>17 reason of trying to get a predetermined result?</p> <p>18 A. I didn't say --</p> <p>19 MR. BISHOP: Sorry. Objection. Argumentative.</p> <p>20 THE WITNESS: I didn't say it demonstrated.</p> <p>21 I said it raises a concern.</p>	<p style="text-align: right;">Page 65</p> <p>1 "To get a predetermined result." Okay?</p> <p>2 I want to use your whole sentence.</p> <p>3 "That manipulated data to get predetermined</p> <p>4 results."</p> <p>5 That's a pretty serious thing to accuse a</p> <p>6 scientist of doing; correct?</p> <p>7 A. It's a concern.</p> <p>8 Q. Okay. But if somebody -- if somebody had</p> <p>9 manipulated data in order to get a predetermined result</p> <p>10 in a published study, that would be a serious thing;</p> <p>11 true?</p> <p>12 A. So it depends. It depends on what kind of</p> <p>13 manipulation is done.</p> <p>14 Q. Okay.</p> <p>15 A. If you're making up data, that's a serious</p> <p>16 concern. If you're -- if you're performing a thought</p> <p>17 experiment -- which is what this paper is -- that's less</p> <p>18 of a concern from a -- from a professional standpoint.</p> <p>19 My -- that sentence there is not saying that they made</p> <p>20 up data. That sentence is saying that they have</p> <p>21 employed a strategy to fill in missing data, which, when</p>

<p style="text-align: right;">Page 66</p> <p>1 they do this and interpret the results, it raises the      2 concern that there was a predetermined result because      3 they failed to address any of the other models.      4 Q. We're going to talk about that.      5 MR. BISHOP: Let him finish.      6 MR. TISI: I thought he was finished. I thought      7 he was finished.      8 BY MR. TISI:      9 Q. Are you finished?      10 A. No.      11 They failed to address any of the other models      12 and used one of the models that is based on a lot of      13 assumptions to perform the rest of their study. And so      14 that is why it raises the concern that there's a      15 predetermined result.      16 Q. Okay. So what I'm -- what I am asking you: You      17 have a concern. You did nothing to investigate it;      18 true?      19 You didn't contact the authors. You didn't      20 speak to anybody. You didn't ask them for any      21 additional information. You didn't ask them for the</p>	<p style="text-align: right;">Page 68</p> <p>1 A. If you could refer to the authors' --      2 Q. O'Brien.      3 A. -- names, that would be great.      4 Q. O'Brien?      5 A. So O'Brien 2024, Chang 2024, those are the      6 main --      7 Q. O'Brien 2020.      8 A. O'Brien 2020. I'm sorry. Chang 2024 and      9 O'Brien 2024 --      10 Q. All right.      11 A. -- were the main studies that added to my      12 opinions.      13 Q. And these are authors from the -- from the      14 National Institute of Environmental Health Sciences --      15 right? -- a division of the NIH?      16 A. I don't specifically recall all of the authors      17 affiliations on those specific papers.      18 Q. Do you know who Dale Sandler is?      19 A. I do not.      20 Q. Do you know who she is?      21 A. No.</p>
<p style="text-align: right;">Page 67</p> <p>1 study -- the study plan. You didn't do anything to      2 investigate the concern.      3 You just threw it out there as a potential      4 concern; true?      5 MR. BISHOP: Object. Argumentative. Also      6 compound.      7 THE WITNESS: It is a potential concern.      8 BY MR. TISI:      9 Q. Right.      10 Did you do anything to investigate it?      11 A. No.      12 Q. Okay.      13 (Jessica Davidson joined via Zoom.)      14 (Off the record.)      15 BY MR. TISI:      16 Q. Okay. All right. Let's talk about the      17 post-2019 evidence.      18 One of the things that happens at your MDL      19 deposition in 2019 were publications by scientists at      20 the National Cancer Institute and the National Institute      21 of Environmental Health Sciences; true?</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. Do you know she's the director of epidemiology      2 at the National -- NEIHS?      3 MR. BISHOP: If he doesn't know whom she is,      4 he's not going to know that. But go ahead.      5 MR. TISI: Thank you. I'm going to go ahead.      6 Please do not speak.      7 THE WITNESS: I said that I didn't know who that      8 was, so I would not know that.      9 BY MR. TISI:      10 Q. So you didn't investigate in any way the      11 credentials of the -- of the authors of these various      12 studies?      13 A. I did not.      14 Q. Now, J&amp;J in its pleadings in the court have      15 called these scientists "preeminent scientists."      16 Do you know -- do you consider them to be      17 preeminent scientists?      18 A. I don't know them at all, so I would not be      19 considering that in a -- in speaking of them.      20 Q. You -- we talked a little bit about IARC before.      21 Do you know that these scientists have actually</p>

<p style="text-align: right;">Page 70</p> <p>1 been asked by the International Agency For Research on      2 Cancer to actually be on the panel looking at the      3 talc/ovarian cancer connection?      4 Do you know that?      5 A. I was not aware of that.      6 Q. I'm going to show you what I have marked as      7 Exhibit Number 12.      8 (Deposition Exhibit 12 was marked.)      9 BY MR. TISI:      10 Q. Which is the list of participants in the IARC      11 process, which is going on as we speak, and ask --      12 MR. TISI: I'm sorry. I think I only have one      13 copy, for some reason. I thought I had several. I'll      14 give you a copy afterwards.      15 BY MR. TISI:      16 Q. Do you know any of these doctors? You see where      17 Dr. O'Brien and Dr. Wentzensen are on the panel;      18 correct?      19 A. I see both of those names. Yes.      20 Q. Okay. Do you know whether or not any -- do you      21 know any of the other experts who are on the panel?</p>	<p style="text-align: right;">Page 72</p> <p>1 A. I do, yes.      2 Q. All right. And that is a new study from when we      3 last met in 2019; correct?      4 A. That's my recollection. Yes.      5 Q. All right. And I am going to give you and      6 counsel a copy. I think we're 13; right?      7 (Deposition Exhibit 13 was marked.)      8 MS. PARFITT: 13.      9 MR. BISHOP: We are.      10 THE WITNESS: Thanks.      11 MR. BISHOP: Thank you.      12 BY MR. TISI:      13 Q. Okay. And this -- and this article is called      14 "Association of Powder Use in the Genital Area with the      15 Risk of Ovarian Cancer"; correct?      16 A. That's correct.      17 Q. By Katie O'Brien; correct?      18 A. And other authors. Yes.      19 Q. Well, and other authors including Dr. Wentzensen      20 and Dr. Sandler.      21 Do you see that?</p>
<p style="text-align: right;">Page 71</p> <p>1 A. Do I know them? No.      2 Q. Do you know of them?      3 A. I do not.      4 Q. Do you have any -- do you see anyone on this      5 list who you have reason to believe would apply a flawed      6 or improper methodology in assessing the risk of talc      7 and ovarian cancer?      8 MR. BISHOP: Objection. Calls for speculation.      9 THE WITNESS: I have no idea how to answer that.      10 I don't know any of these people. So...      11 BY MR. TISI:      12 Q. Do you think any of these people are biased?      13 MR. BISHOP: Same objection.      14 THE WITNESS: I can't answer that. I have no      15 idea.      16 BY MR. TISI:      17 Q. Okay. Let's talk about the O'Brien 2020, if we      18 could. You addressed that in your report on pages 30      19 and 31.      20 Do you see that? You address O'Brien 2020 in      21 the -- in your report.</p>	<p style="text-align: right;">Page 73</p> <p>1 A. Yes, I do.      2 Q. Okay. And the corresponding author is at the      3 O'Brien -- I asked you before, which he was. It's the      4 epidemiology branch at the National Institute of      5 Environmental Health Sciences.      6 Do you see that?      7 A. I do, yes.      8 Q. And on the back, as you would -- as you would      9 expect -- of the article, there's a corresponding where      10 you could actually reach out and ask her questions about      11 this study; right?      12 A. I don't see that. Where is that that you're      13 referring to?      14 Q. Actually, let's move on because I don't want to      15 look for it right now.      16 Typically speaking, there are what's called      17 "corresponding authors" where other professionals can      18 reach out and ask questions?      19 A. Yeah. The usual process is to have a      20 corresponding author, and you either give an address,      21 phone number, email, or something of those natures.</p>

<p style="text-align: right;">Page 74</p> <p>1 Q. Now, according to you on page 31 of your report,      2 it says that these NEIHS authors strongly rebut that      3 cosmetic talc hypothesis because they collected more      4 women, have greater statistical power, and followed      5 these women for a far longer period of time than the      6 prior study but found no association; correct?</p> <p>7 A. That's correct.</p> <p>8 Q. And you rely on this study and these authors as      9 authoritative; correct?</p> <p>10 A. I don't really know what that means. In -- in      11 medicine, we don't typically use that. This is a --      12 this is a paper. There is a way that I would read it      13 and look at the study design, look at the analysis, look      14 at the interpretation of analysis, and what's written.</p> <p>15 You know, I don't really understand what the      16 term "authoritative" means.</p> <p>17 This is a paper that I've used to formulate an      18 opinion.</p> <p>19 Q. Okay. Do you consider this to be a credible      20 study and a credible journal?</p> <p>21 A. Well, I think JAMA is a journal that I do go to</p>	<p style="text-align: right;">Page 76</p> <p>1 by authors from the NIH?</p> <p>2 Q. Um-hum.</p> <p>3 A. I'm sure I have.</p> <p>4 Q. Okay. Have you reviewed any papers by these      5 authors?</p> <p>6 A. Not that I recall.</p> <p>7 Q. Okay. So let's talk a little bit about what      8 these study authors did and why they did it and what the      9 conclusions were, if I could do that for a moment.</p> <p>10 This combines data from three studies, the      11 Women's Health Initiative, The Nurses' Health Study, and      12 the Sister Study; true?</p> <p>13 A. It's actually four studies because it includes      14 the Nurses' Health II, which is a little bit different      15 than Nurses' Health I.</p> <p>16 Q. Okay. And before we talk about what they did      17 together, let's talk about what they talked about these      18 studies individually.</p> <p>19 Were they individually -- did the authors here      20 say that any of the studies -- well, first of all, in      21 your prior report, you said that these cohort studies</p>
<p style="text-align: right;">Page 75</p> <p>1 read papers.</p> <p>2 Q. Okay.</p> <p>3 A. And the design and analysis and interpretation      4 in general, I find I agree with.</p> <p>5 Q. And this is a pooled study; correct?</p> <p>6 A. Well, this is a -- it is a pooled study of      7 cohorts.</p> <p>8 Q. Correct.</p> <p>9 A. So in essence, it is a cohort study.</p> <p>10 Q. Okay. Well, it says -- okay. If it was being      11 called a pooled study by the authors, would you have a      12 reason to disagree?</p> <p>13 A. Only in the fact that it is a cohort study. So      14 it's a longitudinal study. And I would -- if I was      15 reviewing it, I would -- I would ask for further      16 clarification in a -- in either the abstract or in the      17 abstract plus in the body to include that -- that term,      18 "longitudinal."</p> <p>19 Q. Have you ever reviewed any papers submitted by      20 these authors or any authors from the NIH?</p> <p>21 A. Have I reviewed papers that have been submitted</p>	<p style="text-align: right;">Page 77</p> <p>1 individually were sufficient enough to conclude that      2 there was no association.</p> <p>3 Remember that?</p> <p>4 A. I would have to see. I don't have any report      5 memorized.</p> <p>6 Q. Right. But it says what it says; right?</p> <p>7 It says -- your report -- I think previously you      8 discussed the cohort studies, and you discussed the      9 Women's Health Initiative, The Nurses' Study, and the      10 Sister Study in those prior reports because they were      11 available at that time; right?</p> <p>12 A. That's correct.</p> <p>13 Q. All right. And your overall conclusion of those      14 studies, when looked at individually, did not show an      15 association; correct? And you found that to be      16 compelling evidence of no association; true?</p> <p>17 MR. BISHOP: Objection. Asked and answered.</p> <p>18 And he asked to see his report, where he says it.</p> <p>19 MR. TISI: Thank you very much, but please stop.</p> <p>20 MR. BISHOP: I'm -- that's exactly how he      21 testified earlier.</p>

<p style="text-align: right;">Page 78</p> <p>1        THE WITNESS: Can you ask that again?</p> <p>2 BY MR. TISI:</p> <p>3    Q. Yes.</p> <p>4        In your prior report, you testified that each of</p> <p>5 those studies individually were evidence that there was</p> <p>6 no association; true?</p> <p>7        MR. BISHOP: Same objection.</p> <p>8        THE WITNESS: So in my report, I think I</p> <p>9 summarized the -- the point estimates and the confidence</p> <p>10 intervals --</p> <p>11 BY MR. TISI:</p> <p>12    Q. Right.</p> <p>13    A. -- investigating the potential association</p> <p>14 between cosmetic talc and ovarian cancer, and I provided</p> <p>15 those point estimates and confidence intervals.</p> <p>16    Q. Right.</p> <p>17       And before the -- before this pooled study with</p> <p>18 this longitudinal study of O'Brien 2020, you felt that</p> <p>19 the individual cohort studies, as reported by Houghton</p> <p>20 and Gates and Gertig and Gonzalez were sufficient to</p> <p>21 concluding that there was no association based on those</p>	<p style="text-align: right;">Page 80</p> <p>1        risk in the United States -- and individual cohort</p> <p>2 studies are not sufficiently powered to detect modest</p> <p>3 associations, particularly restricted to susceptible</p> <p>4 subgroups, such as women with patent reproductive</p> <p>5 tracts."</p> <p>6        Do you see that?</p> <p>7    A. I do see that.</p> <p>8    Q. And so what they were saying was, look, one of</p> <p>9 the reasons why they pulled it together is because the</p> <p>10 individual studies didn't -- weren't really powered;</p> <p>11 correct?</p> <p>12    A. Well, there's no calculation there. And so</p> <p>13 I don't know that. That's what's written there, but</p> <p>14 they don't give us that calculation.</p> <p>15       And, to me, when I interpret that this is just</p> <p>16 when you write a paper, you write sort of about why it's</p> <p>17 important for the next paper to be done. And</p> <p>18 I interpret that sentence as, hey, you know, we're not</p> <p>19 really sure, and so we're going to put all these studies</p> <p>20 together because it brings in four large groups that are</p> <p>21 followed longitudinally to try to get at this question.</p>
<p style="text-align: right;">Page 79</p> <p>1 cohorts; true?</p> <p>2        MR. BISHOP: Same objection.</p> <p>3        THE WITNESS: So they individually did add to my</p> <p>4 opinion that there was no causal association --</p> <p>5 BY MR. TISI:</p> <p>6    Q. All right.</p> <p>7    A. -- between cosmetic talcum powder and ovarian</p> <p>8 cancer.</p> <p>9    Q. And, overall, you felt that the cohorts --</p> <p>10 individually and then looked at as a body -- were</p> <p>11 inconsistent with the case control studies, and that was</p> <p>12 important to you back then; correct?</p> <p>13    A. And it still is important to me today.</p> <p>14    Q. Okay. And -- but the authors in O'Brien 2020</p> <p>15 disagreed with that, did they not?</p> <p>16    A. You'd have to show me what you're referring to.</p> <p>17    Q. On page 50 -- on page 50, it says, "To date,</p> <p>18 three large cohort studies have assessed the association</p> <p>19 between the use of powder in the genital area and</p> <p>20 ovarian cancer risk with inconsistent results. However,</p> <p>21 ovarian cancer is a rare disease -- 1.3 percent lifetime</p>	<p style="text-align: right;">Page 81</p> <p>1    Q. Right.</p> <p>2       But they said the individual studies weren't</p> <p>3 powered; true?</p> <p>4    A. That's what it says. But there's no calculation</p> <p>5 there --</p> <p>6    Q. I understand.</p> <p>7    A. -- and so I can't -- I didn't do the</p> <p>8 calculations myself. The calculations aren't there. We</p> <p>9 have no idea. That's what they're saying, but there's</p> <p>10 no calculation.</p> <p>11    Q. Right.</p> <p>12       And that point was actually made by plaintiffs'</p> <p>13 experts in the original thing that you criticized back</p> <p>14 in 2019. You thought that they were powered; correct?</p> <p>15       And they said they weren't powered, "they" being</p> <p>16 plaintiffs' experts. And now we find that the authors</p> <p>17 of those -- of these studies disagreed with you on that</p> <p>18 point; true?</p> <p>19       MR. BISHOP: I'm sorry. Objection because it</p> <p>20 violates the order that this is to be only --</p> <p>21       MR. TISI: Does not.</p>

<p style="text-align: right;">Page 82</p> <p>1       MR. BISHOP: It does.</p> <p>2       MR. TISI: No. This is a new study.</p> <p>3       MR. BISHOP: It is. But you're now asking him</p> <p>4       to comment on the prior study --</p> <p>5       MR. TISI: I'm not fighting -- I'm not fighting</p> <p>6       you on that.</p> <p>7       MR. BISHOP: You may -- you can say that all you</p> <p>8       want. I can state the objection.</p> <p>9       MR. TISI: Okay.</p> <p>10      MR. BISHOP: You're not entitled to go back and</p> <p>11      try to summarize his prior testimony.</p> <p>12      MR. TISI: I'm not. I'm not.</p> <p>13      THE WITNESS: So my recollection on the power</p> <p>14      calculations, in doing so, there are a lot of</p> <p>15      assumptions that go into doing power calculations, and</p> <p>16      one of them is looking at the incidence of ovarian</p> <p>17      cancer. And some of the power calculations, from my</p> <p>18      recollection, by plaintiffs' experts used a different</p> <p>19      incidence of ovarian cancer than the incidence in these</p> <p>20      four studies.</p> <p>21</p>	<p style="text-align: right;">Page 84</p> <p>1       MR. TISI: Keep going --</p> <p>2       MR. BISHOP: Now you're trying to go back --</p> <p>3       MR. TISI: Keep going --</p> <p>4       MR. BISHOP: -- and summarize his testimony.</p> <p>5       (Indistinguishable simultaneous speaking;</p> <p>6       reporter admonishment.)</p> <p>7       MR. TISI: I understand. "Objection" is fine.</p> <p>8       BY MR. TISI:</p> <p>9       Q. You may answer.</p> <p>10      A. I would have to look exactly as to what I said</p> <p>11      and read my deposition. I don't specifically recall the</p> <p>12      exact numbers in the power calculation. I know I did</p> <p>13      power calculations, and I don't disagree with what</p> <p>14      I said back then.</p> <p>15      Q. Okay. But now, the authors in 2020 said the</p> <p>16      individual studies were not powered, and so now they're</p> <p>17      combining them?</p> <p>18      A. That's what --</p> <p>19      MR. BISHOP: Objection. Asked and answered.</p> <p>20      THE WITNESS: That's what that sentence says.</p> <p>21</p>
<p style="text-align: right;">Page 83</p> <p>1       BY MR. TISI:</p> <p>2       Q. Okay.</p> <p>3       A. These studies are enriched because they're older</p> <p>4       individuals. The Sister Study is enriched because</p> <p>5       there's a family history of cancer. And so using the</p> <p>6       12.1 cases of ovarian cancer per 100,000 as the</p> <p>7       incidence is a flawed assumption.</p> <p>8       Q. Okay.</p> <p>9       A. And so to actually do the power calculations</p> <p>10      again -- and it's a moot point, because this study,</p> <p>11      putting all these --</p> <p>12      Q. I agree with you.</p> <p>13      A. -- together has plenty of people and plenty of</p> <p>14      time to get at the answer.</p> <p>15      Q. I gotcha. And we're going to talk about that.</p> <p>16      But, previously, you testified that the</p> <p>17      individual studies sufficiently show that there was no</p> <p>18      association. There was a dispute about that.</p> <p>19      You remember that; right?</p> <p>20      MR. BISHOP: I'm sorry. Again, that violates</p> <p>21      the Court order --</p>	<p style="text-align: right;">Page 85</p> <p>1       BY MR. TISI:</p> <p>2       Q. Okay.</p> <p>3       A. But there is no calculation there. And if</p> <p>4       they're using the incidence of ovarian cancer of 12.1</p> <p>5       per 100,000, which is what it was at that time, then</p> <p>6       that is a flawed assumption and I would disagree with</p> <p>7       that statement.</p> <p>8       BY MR. TISI:</p> <p>9       Q. So -- okay. That's fine. That's what I wanted.</p> <p>10      So, now, pulling these studies together, the</p> <p>11      authors in O'Brien 2020 found the overall increased risk</p> <p>12      of 80 percent for women but found it was not</p> <p>13      statistically significant, i.e., the confidence interval</p> <p>14      was below 1. It started at .99 and went to 1.25;</p> <p>15      correct?</p> <p>16      A. What are you referring to?</p> <p>17      Q. I'm referring to the overall results of the</p> <p>18      study.</p> <p>19      A. And where are you reading that from? In the</p> <p>20      paper, if you could just point it to me, that would be</p> <p>21      great.</p>

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1 Q. Yeah, yeah.	1 association; correct?
2 The overall results were 1.08 with a confidence	2 A. That's what I just said.
3 interval of .99 to 1.17.	3 Q. Okay. Now, that overall result included both
4 Do you see that? It's in the very -- the	4 women with open tubes and women who had had, for
5 results section of the paper. It's actually in your	5 example, hysterectomies and did not have an open
6 report.	6 reproductive tract; true?
7 A. So I'm -- I'm reading ovarian cancer incidence	7 A. It included both patent and nonpatent
8 and then I'll skip to an estimated hazard ratio of 1.08,	8 reproductive tracts.
9 95 percent confidence interval, .99 to 1.17.	9 Q. Okay. And so if you go to page 31 of your
10 Q. Just so anybody reading this could understand,	10 report, it says, last sentence, "In sum, O'Brien
11 if the confidence interval, hypothetically, was 1.01	11 strongly rebuts that the cosmetic talc/ovarian cancer
12 instead of .99, it would have been statistically	12 hypothesis because it collected more women had far
13 significant, in your view?	13 greater statistical power and followed these women for
14 A. So, mathematically, if the confidence interval	14 far longer a period of time than any prior study but
15 did not cross over 1, it would be statistically	15 found no association."
16 significant.	16 A. That's correct.
17 Q. Right.	17 Q. Okay. You believe that the authors believe that
18 So the point -- going from .99 to 1.01 would	18 there was no association?
19 have, in your mind, changed the overall results of the	19 A. I do, yes.
20 study and made it a true association?	20 Q. Okay. Have you seen statements that the authors
21 A. No. Not necessarily. Statistical significance	21 actually disagree with that?
Page 87	Page 89
1 is not the only thing. We also have to look at the	1 A. I have not.
2 strength of association and a 1.08 point estimate is a	2 Q. I'd like to show you Exhibit Number 17.
3 very, very, very weak --	3 (Deposition Exhibit 14 was marked.)
4 Q. I'm not talking about --	4 MS. PARFITT: 17? 14.
5 A. -- association.	5 MR. TISI: I'm sorry. And this will be
6 Q. -- I'm not talking about the strength of	6 Exhibit Number 14.
7 association.	7 BY MR. TISI:
8 I'm talking about in terms of whether it would	8 Q. Now, do you understand, Doctor, that in
9 be a statistically significant association, it would	9 typically -- particularly with papers like this, there
10 have been, in your mind, if the confidence interval was	10 would be opportunities for people like yourself, if you
11 1.01, as opposed to .99, that would have been a	11 were so inclined, to write letters to the editor
12 statistically significant association, and then we would	12 regarding papers?
13 have talked about issues like strength; true?	13 A. Am I aware that you have the opportunity to
14 A. And I think that's what I said.	14 write letters to the editor? Yes.
15 Q. Okay.	15 Q. Um-hum.
16 A. If it was -- if the confidence interval did not	16 And, oftentimes, the authors will actually
17 cross 1, which it does, then mathematically, it would be	17 respond to the letters that are written about papers
18 a statistically significant association.	18 that they write?
19 Q. And so mathematically, if the numbers were a	19 A. Usually you have the opportunity to respond to
20 1.08 relative risk with a 1.01 confidence interval lower	20 letters to the editor. Yes.
21 bounds, that would have been a statistically significant	21 Q. And that's part of the iterative process of

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<p style="text-align: right;">Page 90</p> <p>1 science; true?</p> <p>2 A. Sometimes. Sometimes it's -- just becomes</p> <p>3 argumentative. But, in general, it allows someone to</p> <p>4 comment and give their opinion about a paper, a</p> <p>5 manuscript.</p> <p>6 Q. It actually allows authors to maybe clarify some</p> <p>7 things that they might have otherwise -- might be</p> <p>8 misinterpreted?</p> <p>9 A. I mean, it gives a lot of opportunities to do a</p> <p>10 lot of things. Yes.</p> <p>11 Q. Okay. All right. So let's see -- have you seen</p> <p>12 the letters to the editor regarding the O'Brien paper?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And you know, that, for example,</p> <p>15 Drs. Harlow and Dr. Rothman wrote a letter to the editor</p> <p>16 about some of the issues that were contained in the</p> <p>17 paper --</p> <p>18 A. That's correct.</p> <p>19 Q. -- true?</p> <p>20 All right. And Dr. Rothman actually wrote a</p> <p>21 textbook on -- that we've talked about last time</p>	<p style="text-align: right;">Page 92</p> <p>1 BY MR. TISI:</p> <p>2 Q. You do not. Okay.</p> <p>3 So they wrote a letter to the editor. And let's</p> <p>4 see what doctors -- Dr. O'Brien and Wentzensen and</p> <p>5 Sandler say here.</p> <p>6 Now, you don't reference this letter to the</p> <p>7 editor in your report, do you? Or Dr. O'Brien's comp</p> <p>8 response?</p> <p>9 A. No. I think I reference an editorial by</p> <p>10 Gossett.</p> <p>11 Q. How about -- why don't you refer to the</p> <p>12 statements of the actual authors of the study made about</p> <p>13 the study that they wrote?</p> <p>14 A. Can you ask that again?</p> <p>15 Q. Yes.</p> <p>16 Why are you referring to an editorial by Gossett</p> <p>17 when you could be looking at what the authors themselves</p> <p>18 actually say about their own study in the response to</p> <p>19 the letter to the editor?</p> <p>20 A. Because it was a power calculation that was</p> <p>21 performed by Gossett.</p>
<p style="text-align: right;">Page 91</p> <p>1 relating to epidemiology; right? He's pretty well-known</p> <p>2 guy?</p> <p>3 MR. BISHOP: Objection. Covers what was covered</p> <p>4 in the prior deposition. Let's move on.</p> <p>5 THE WITNESS: Yeah, I don't --</p> <p>6 BY MR. TISI:</p> <p>7 Q. You don't know who he is?</p> <p>8 A. I don't know Dr. Harlow.</p> <p>9 Q. No. I didn't say Dr. Harlow. I said</p> <p>10 Dr. Rothman.</p> <p>11 A. I don't --</p> <p>12 MR. BISHOP: Same objection. Covered</p> <p>13 extensively in the last deposition.</p> <p>14 BY MR. TISI:</p> <p>15 Q. You never heard Dr. Rothman's name?</p> <p>16 A. I said I didn't know Dr. Rothman.</p> <p>17 Q. I didn't ask you if you know him. Do you know</p> <p>18 him by reputation?</p> <p>19 MR. BISHOP: Same objection. Covered</p> <p>20 extensively in the last deposition.</p> <p>21 THE WITNESS: No, I do not.</p>	<p style="text-align: right;">Page 93</p> <p>1 Q. Okay. So let me ask you the question. Would it</p> <p>2 be important to you to understand what the authors said</p> <p>3 about their own study?</p> <p>4 MR. BISHOP: Objection. Vague. Overbroad.</p> <p>5 THE WITNESS: So it depends.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Okay.</p> <p>8 A. It really depends on what is said and in the</p> <p>9 letter to an editor, which is also not peer reviewed.</p> <p>10 Q. Okay. The letter says -- and, Doctor, let's</p> <p>11 read it together. You see where it says, "We never</p> <p>12 equated the lack of statistical significance as evidence</p> <p>13 of no association"?</p> <p>14 Do you see where the authors say that?</p> <p>15 A. Can you show me where that is?</p> <p>16 Q. Yeah. End of the second paragraph, starting</p> <p>17 with, "We completely agree with Drs. Harlow and</p> <p>18 colleagues that our results, particularly the analysis</p> <p>19 limited to women with intact reproductive tracts, should</p> <p>20 not be discounted because of lack of statistical</p> <p>21 significance."</p>

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<p>1 Do you see that?</p> <p>2 A. I'm sorry. Which page are you on? I'm trying</p> <p>3 to -- there are --</p> <p>4 Q. Page -- the second page.</p> <p>5 A. There are three pages here.</p> <p>6 Q. The second page, where they're responding --</p> <p>7 where they, Dr. -- Drs. O'Brien, Sandler, and Wentzensen</p> <p>8 are actually responding to the letter written by</p> <p>9 Drs. Harlow and Rothman.</p> <p>10 A. Okay. So the third page of this document that</p> <p>11 you're showing?</p> <p>12 Q. Yes. The third page.</p> <p>13 And it says, "The first full paragraph, we</p> <p>14 completely agree with Dr. Harlow and colleagues that our</p> <p>15 results, particularly the analysis limited to women with</p> <p>16 intact reproductive tracts, should not be discounted</p> <p>17 because of lack of statistical significance."</p> <p>18 Do you see that?</p> <p>19 A. I do.</p> <p>20 Q. And at the very end of the paragraph, it says,</p> <p>21 "We never equated the lack of statistical significance</p>	<p>1 A. I do. And that is a completely hypothetical</p> <p>2 statement.</p> <p>3 Q. They said -- they didn't say it's a</p> <p>4 hypothetical. They said it's likely; true?</p> <p>5 A. No. They say "may lie somewhere in the middle."</p> <p>6 Q. It's "The true -- the true association may lie</p> <p>7 somewhere -- lie somewhere in the middle."</p> <p>8 Do you see that?</p> <p>9 A. I do, yes.</p> <p>10 Q. And it said -- and then they go on to say, at</p> <p>11 the very bottom, it says, "We agree" -- the next</p> <p>12 paragraph, beginning with, "We conducted subgroup</p> <p>13 analyses."</p> <p>14 They said, "Even though we stated the findings</p> <p>15 from the subgroup analysis should be interpreted as</p> <p>16 exploratory, we do not consider them all equally</p> <p>17 important and agree that the positive association</p> <p>18 amongst women with patent reproductive tracts is</p> <p>19 consistent with the hypothesis that there is an</p> <p>20 association between genital powder use and ovarian</p> <p>21 cancer."</p>
Page 95	Page 97
<p>1 to be evidence of no association."</p> <p>2 A. I do see that.</p> <p>3 Q. Okay. Now, you said in your report that this</p> <p>4 provided evidence of no association.</p> <p>5 That's not what these authors said, is it?</p> <p>6 A. There is no statistical significance.</p> <p>7 Q. Well --</p> <p>8 A. And the point estimate is -- is very low, and so</p> <p>9 I disagree with that --</p> <p>10 Q. Okay.</p> <p>11 A. -- that there is -- there is no association.</p> <p>12 Q. So you disagree with the authors of the study</p> <p>13 about the interpretation of their own study?</p> <p>14 A. I do, yes.</p> <p>15 Q. Okay. Next thing, if you go to the top, it</p> <p>16 says, "If cohort studies (pooled hazard ratio 1.08) is</p> <p>17 likely biased between the null and case control studies</p> <p>18 (meta-analyses, odds ratio, 1.35) are likely biased away</p> <p>19 from the null, the true association is likely somewhere</p> <p>20 in the middle."</p> <p>21 Do you see that?</p>	<p>1 Do you see that?</p> <p>2 A. I do see that.</p> <p>3 Q. Okay. And I assume you disagree with the</p> <p>4 authors with their study about the interpretations of</p> <p>5 their own study?</p> <p>6 A. I do. There was no difference between --</p> <p>7 Q. Okay.</p> <p>8 A. -- the hazard ratio in women with patent or</p> <p>9 nonpatent reproductive tracts that was a statistically</p> <p>10 nonsignificant difference.</p> <p>11 So, yes, I disagree with that.</p> <p>12 Q. Okay. So I asked you before whether or not</p> <p>13 you'd seen any evidence that the authors of the O'Brien</p> <p>14 2024 study disagreed with your conclusion that there was</p> <p>15 no association -- their own interpretation in real-time</p> <p>16 would mitigate against that; true?</p> <p>17 A. I'm sorry. Can you just ask that again?</p> <p>18 Q. Yes.</p> <p>19 A. I didn't get what you're asking me.</p> <p>20 Q. You said that, in sum, O'Brien strongly rebuts</p> <p>21 the cosmetic talc ovarian cancer hypothesis, and you</p>

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<p>1 posit that the study itself found no association; right?</p> <p>2 A. In my interpretation, yes.</p> <p>3 Q. Yeah. And the authors of the study disagree</p> <p>4 with that, based upon -- in their letter to the editor?</p> <p>5 A. Not -- not necessarily. Point to where you're</p> <p>6 seeing that.</p> <p>7 Q. Well, they said -- we went through it.</p> <p>8 But you disagree with their -- with what they</p> <p>9 say about their own study in the response to Dr. Harlow</p> <p>10 and Dr. Rothman; true?</p> <p>11 MR. BISHOP: Object to the form. Vague.</p> <p>12 Overbroad. Asked and answered.</p> <p>13 THE WITNESS: Can you ask that one more time?</p> <p>14 BY MR. TISI:</p> <p>15 Q. Yes.</p> <p>16 A. Because I'm --</p> <p>17 Q. We went through several comments that they made</p> <p>18 in response to Drs. Harlow and Rothman in their response</p> <p>19 to the letter of the editor about their own study; true?</p> <p>20 A. That's correct.</p> <p>21 Q. Okay. And you disagreed with them; true?</p>	<p>1 important?</p> <p>2 A. I think it depends.</p> <p>3 Q. Okay.</p> <p>4 A. It depends on what you find, and it depends on</p> <p>5 the, really, other factors that go into the framework of</p> <p>6 Bradford Hill.</p> <p>7 Q. Okay. Let's look at page 51 of the study. In</p> <p>8 the second column, third paragraph down. It says,</p> <p>9 "Because patency is required for there to be direct</p> <p>10 physical pathway between the powder application area and</p> <p>11 the ovaries, we hypothesize a priori that women with</p> <p>12 patent reproductive tracts would be more susceptible to</p> <p>13 the effect of powder in the genital area on ovarian</p> <p>14 cancer."</p> <p>15 Do you see that?</p> <p>16 A. I do, yes.</p> <p>17 Q. So they looked at it ahead of time? They</p> <p>18 decided to do this analysis ahead of time; right?</p> <p>19 A. Yes. That's what they're saying. Yes.</p> <p>20 Q. For good reason. If you have a patent -- if you</p> <p>21 have an intact reproductive tract, they said that would</p>
<p>1 MR. BISHOP: Same objection.</p> <p>2 THE WITNESS: I -- I answered that I disagree</p> <p>3 with the interpretation of --</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay.</p> <p>6 A. -- of their results.</p> <p>7 Q. Now, in addition, the authors talked about --</p> <p>8 that they explored women with reproductive tracts;</p> <p>9 correct?</p> <p>10 A. Can you show me what you're referring to?</p> <p>11 Q. You don't know that they -- do you know whether</p> <p>12 or not they looked at a subgroup of women with intact</p> <p>13 reproductive tracts?</p> <p>14 A. There was a subgroup analysis. Yes.</p> <p>15 Q. Okay. And you know that that was done a priori?</p> <p>16 They did it ahead of time; correct?</p> <p>17 A. I don't specifically recall if they used that</p> <p>18 word. But I know that it was a subgroup analysis.</p> <p>19 Q. Well, what's -- is a difference between</p> <p>20 something you decide to do ahead of time and something</p> <p>21 you do afterwards, in terms of reliability, is that</p>	<p>1 be a way in which talc would get to the ovaries; right?</p> <p>2 A. I mean, if you believe that, yes.</p> <p>3 Q. Well, okay. Then the next thing it says,</p> <p>4 "Therefore, we conducted an analysis restricted to the</p> <p>5 subgroup. When estimating the effect of duration of</p> <p>6 powder on the ovarian cancer risk, we compared</p> <p>7 long-term, greater than 20 years, and non-long-term</p> <p>8 users with never users. Similarly, we compared frequent</p> <p>9 users and non-frequent users with never users. We</p> <p>10 conducted trend tests using the ordinal forms of these</p> <p>11 values."</p> <p>12 Do you see that?</p> <p>13 A. I do, yes.</p> <p>14 Q. All right. And when they looked at that, they</p> <p>15 found a statistically significant risk; correct?</p> <p>16 A. And which -- which one are you referring to?</p> <p>17 Q. Well, they -- if you go to figure 5 -- I'm</p> <p>18 sorry. Figure -- on page 54, it shows a statistically</p> <p>19 significant increased risk with women with open</p> <p>20 reproductive tracts of 1.13; correct?</p> <p>21 A. Yes. 1.13 with confidence interval of 1.01 to</p>

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<p style="text-align: right;">Page 102</p> <p>1 1.26. And when they compared that to the nonpatent      2 reproductive tracts, which had a hazard ratio of .99,      3 there was no statistically significant difference      4 between those two groups.</p> <p>5 Q. Okay. I'm going to move to strike the      6 nonresponsive portion of the question -- of your answer.</p> <p>7 Then they go on to say, on page 56 of O'Brien      8 2020, it says, "by" -- on the right-hand side, "By      9 irritating epithelial ovarian tissue on fallopian tubes      10 directly, powder could influence an inflammatory      11 response, even in the absence of asbestos. This could      12 set off a cascade of increased oxidative stress level,      13 DNA damage, and cell division, all of which could      14 contribute to carcinogenesis."</p> <p>15 Did I read that correctly?</p> <p>16 A. You did.</p> <p>17 Q. Okay. That -- they are giving a biologically      18 plausible mechanism for the possibility that talc could      19 cause ovarian cancer, are they not?</p> <p>20 MR. BISHOP: Objection. Foundation.</p> <p>21 THE WITNESS: They are -- they are</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. Yes.</p> <p>2 I asked you whether you reviewed what      3 Dr. O'Brien and Wentzensen and Sandler said about their      4 2020 study and your conclusion that the study provided      5 evidence of, quote, "no association."</p> <p>6 MR. BISHOP: Object. He's answer --</p> <p>7 BY MR. TISI:</p> <p>8 Q. You remember that -- you remember I asked you      9 about that?</p> <p>10 MR. BISHOP: Same objection.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Okay. And we looked at the letter that they      14 wrote to the editor. And your response was, well, you      15 disagreed with it, but it wasn't peer reviewed.</p> <p>16 Do you remember that?</p> <p>17 MR. BISHOP: Objection. Mischaracterizes his      18 answer.</p> <p>19 THE WITNESS: I disagree with their      20 interpretation. In reading the conclusion of their      21 paper, they said that there's not a statistically</p>
<p style="text-align: right;">Page 103</p> <p>1 hypothetically providing an explanation that has no      2 basis in epidemiology.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. Well, no basis in epidemiology except      5 that there is an increased risk in women with patent      6 tubes; true?</p> <p>7 A. In subgroup analysis, but not when compared to      8 those who had patent -- or nonpatent reproductive      9 tracts.</p> <p>10 Q. Okay. Then it goes --</p> <p>11 MR. TISI: Okay. We can take a quick break.</p> <p>12 THE WITNESS: Okay.</p> <p>13 (Recess taken.)</p> <p>14 MR. TISI: Let's go back on the record.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Now, I asked you before whether you'd seen other      17 references by Drs. O'Brien, Sandler, and Wentzensen      18 where they disagreed with you that the results of their      19 2020 study showed, quote, "no association."</p> <p>20 Do you remember that?</p> <p>21 A. Can you ask that one more time?</p>	<p style="text-align: right;">Page 105</p> <p>1 significant association between use of powder in the      2 genital area and incidence of ovarian cancer.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. Now, the next -- have you seen any      5 published peer-reviewed literature where they do not --      6 they do not say that there's no association?</p> <p>7 Have you seen that?</p> <p>8 A. I don't specifically recall, but you'd have to      9 show me if there is something.</p> <p>10 Q. I will do that. Let's look at O'Brien 2021.</p> <p>11 (Deposition Exhibit 15 was marked.)</p> <p>12 BY MR. TISI:</p> <p>13 Q. Let me show you Exhibit Number 20 -- Exhibit 15.</p> <p>14 It's entitled "Association Between Douching, Genital      15 Talc Use, and the Risk of Prevalent and Incident      16 Cervical Cancer."</p> <p>17 Have you seen this article before?</p> <p>18 A. I have.</p> <p>19 MR. BISHOP: Got one more?</p> <p>20 MR. TISI: I'm sorry. I thought I --</p> <p>21 MS. PARFITT: I'm sorry. I don't want to throw</p>

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<p>1 to you.</p> <p>2 BY MR. TISI:</p> <p>3 Q. And these are by the same authors; correct?</p> <p>4 Some of the same authors?</p> <p>5 A. O'Brien and Sandler are the ones I recognize.</p> <p>6 Q. Okay. And on the next page, do they not say --</p> <p>7 I'm going to read. It says, "Talc applied to underwear,</p> <p>8 sanitary napkins, diaphragms, or directly to the</p> <p>9 perineal region can enter the vagina and travel up the</p> <p>10 reproductive tract."</p> <p>11 Do you see that on the second page?</p> <p>12 A. I do.</p> <p>13 Q. Goes on to say, "Talcum particles may act as</p> <p>14 irritants, inciting an inflammatory response and</p> <p>15 potentially affecting the individual susceptibility and</p> <p>16 response to HPV infection."</p> <p>17 Do you see that?</p> <p>18 A. I do see that.</p> <p>19 Q. It says, "Additional and more severe adverse</p> <p>20 effects could occur if talc containing asbestos, a known</p> <p>21 carcinogen, sometimes mined in the same location as</p>	<p>Page 106</p> <p>1 association" is.</p> <p>2 That -- that's the same thing as saying a</p> <p>3 possible negative association. It's a possibility.</p> <p>4 It's a hypothesis. It's a guess.</p> <p>5 Q. Okay. Move to strike.</p> <p>6 They are again saying -- they are not saying, as</p> <p>7 you do in your expert litigation report, that their --</p> <p>8 that their study supports the conclusion that there is</p> <p>9 no association; true?</p> <p>10 MR. BISHOP: Object to the form.</p> <p>11 Mischaracterizes.</p> <p>12 THE WITNESS: Can you say that again?</p> <p>13 BY MR. TISI:</p> <p>14 Q. Yeah.</p> <p>15 They are not saying that there's no association</p> <p>16 in this -- based upon O'Brien 2020 and this 2021</p> <p>17 article; true? Like you do.</p> <p>18 A. They are not saying that there is no</p> <p>19 association, but they're not saying that there is an</p> <p>20 association either.</p> <p>21 Q. Okay. You say that that study proves that</p>
<p>1 talc."</p> <p>2 Did I read that right?</p> <p>3 A. You did, yes.</p> <p>4 Q. And it says, "The epidemiologic literature supports</p> <p>5 a positive association between genital talc and ovarian</p> <p>6 cancer."</p> <p>7 Do you see that?</p> <p>8 A. I see, "The epidemiologic literature supports a</p> <p>9 possible positive association between genital talc use</p> <p>10 and ovarian cancer."</p> <p>11 Q. And it cites -- if you look at the cite, it</p> <p>12 cites O'Brien 2020; correct?</p> <p>13 A. I'd have to look at those references.</p> <p>14 Q. Well, look at Exhibit 34 and 35 -- footnote 34</p> <p>15 and 35.</p> <p>16 It cites Terry and O'Brien.</p> <p>17 A. It does. It does. And I don't even know what</p> <p>18 that sentence means, because what it's saying is it says</p> <p>19 "The epidemiologic literature supports a possible --</p> <p>20 possible positive association."</p> <p>21 I don't even know what "a possible positive</p>	<p>Page 107</p> <p>1 there's no association; true?</p> <p>2 A. There's no statistical significant association</p> <p>3 between cosmetic talc use and ovarian cancer in that</p> <p>4 study.</p> <p>5 Q. Okay. Next thing. I'm going to show you an</p> <p>6 article by The Ovarian Cancer Cohort Consortium.</p> <p>7 MS. PARFITT: It's number 16.</p> <p>8 MR. TISI: Number --</p> <p>9 MS. PARFITT: 16.</p> <p>10 (Deposition Exhibit 16 was marked.)</p> <p>11 BY MR. TISI:</p> <p>12 Q. Have you seen this article before by</p> <p>13 Dr. Townsend?</p> <p>14 A. I don't believe so.</p> <p>15 Q. Okay. This is -- do you know what The Ovarian</p> <p>16 Cancer Cohort Consortium is?</p> <p>17 A. Not specifically. I've heard of it, but I don't</p> <p>18 specifically know what it is.</p> <p>19 Q. Okay. Do you see that Dr. Sandler, Dr. O'Brien,</p> <p>20 and Dr. Wentzensen are coauthors?</p> <p>21 A. I do, yes.</p>

<p style="text-align: right;">Page 110</p> <p>1 Q. Okay. And this is a 2021 article as well; 2 correct?</p> <p>3 A. That's correct.</p> <p>4 Q. If you go to the page that I tagged there, there 5 is a statement -- there's no pages. That's why I tagged 6 it. It says, "In the largest prospective study so far, 7 the OC3 found a very small positive association between 8 genital powder use and ovarian cancer risk among all 9 women, (hazard ratio, 1.8; confidence interval, .99 to 10 1.17) as well as among women with an intact uterus and 11 fallopian tubes, (1.13; 95 percent confidence interval; 12 1.01 to 1.26.)</p> <p>13 Do you see that?</p> <p>14 A. I do see that. And those are the results from 15 the O'Brien 2020 study. And what I'll say -- which 16 I said before -- is that that is a nonstatistically 17 significant result. 1.08 has a confidence interval that 18 goes across 1, and there was no difference between those 19 women who had intact reproductive tracts compared to 20 those who didn't.</p> <p>21 And so to say that a very small positive</p>	<p style="text-align: right;">Page 112</p> <p>1 significant association.</p> <p>2 Q. Right. Right.</p> <p>3 But they say that there is a -- they say that 4 there's a small positive association; correct? They 5 don't say that there is no association, like you do; 6 true?</p> <p>7 A. There is no statistically significant 8 association.</p> <p>9 Q. That's not -- that's not what I'm asking you, 10 Doctor, with all due respect.</p> <p>11 When they're reporting the results of this 12 study, they're saying the overall results report a small 13 positive association particularly among women with 14 intact reproductive system; right?</p> <p>15 MR. BISHOP: Objection. Asked and answered.</p> <p>16 THE WITNESS: That's what it's saying. I 17 disagree with the qualitative issues in that sentence.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. And that's fine. You can disagree with 20 it.</p> <p>21 But that's what they're saying about their own</p>
<p style="text-align: right;">Page 111</p> <p>1 association, without talking about statistically 2 significance, is -- is an issue that I have. And I had 3 been reviewing this, I would have pointed that out.</p> <p>4 Q. Okay. Move to strike. There was no question 5 that I asked you about that.</p> <p>6 I asked you whether I read that right.</p> <p>7 A. And you did, and I --</p> <p>8 Q. Okay. So let -- now let me ask you a question.</p> <p>9 I asked you before whether or not the authors of 10 this study themselves have been saying -- have said that 11 there is evidence of an association that would support 12 your contention that there is no association. And I've 13 shown you several articles now, one letter to the 14 editor, one the 2021 study, and now there's a 2021 paper 15 where they say there is a small positive association, 16 particularly among women with an intact fallopian tube 17 and uterus; right? That's what they said; true?</p> <p>18 A. That's what it's saying. Yes.</p> <p>19 Q. Okay. And that -- you disagree with that?</p> <p>20 A. I see what they're saying, that there's a small 21 positive association that is a nonstatistically</p>	<p style="text-align: right;">Page 113</p> <p>1 study; true?</p> <p>2 A. That's what's written down.</p> <p>3 Q. Okay. Next thing -- all right. Let's talk 4 about O'Brien 2024 as well. Let's see if we can move 5 forward.</p> <p>6 Please get Exhibit 3 out, if you would, which is 7 your report.</p> <p>8 MS. PARFITT: It's Exhibit 2.</p> <p>9 MR. TISI: I'm sorry. Oh, I'm sorry. Exhibit 1 10 and 2. I'm sorry.</p> <p>11 THE WITNESS: It's okay.</p> <p>12 MR. TISI: Oh, I'm sorry. I'm actually wrong 13 about that. I previously marked Exhibit 3 the study 14 itself; correct?</p> <p>15 MS. PARFITT: Yes.</p> <p>16 THE WITNESS: Yes.</p> <p>17 MR. TISI: Thank you.</p> <p>18 BY MR. TISI:</p> <p>19 Q. And this is the study that caused you to have -- 20 need additional time to add a section of -- in your 21 report, and that section is on pages 31 to -- 30 to 34.</p>

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<p>1 30 to 33; correct?</p> <p>2 A. I have --</p> <p>3 Q. 30 to 34.</p> <p>4 A. -- 31 through 34.</p> <p>5 Q. Correct.</p> <p>6 A. That's correct.</p> <p>7 Q. Let me get my copy of that.</p> <p>8 Now, just to kind of set the table, this is also</p> <p>9 a study by Dr. O'Brien, Dr. Wentzensen, and Dr. Sandler,</p> <p>10 among others; correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Okay. And this study is -- was published in the</p> <p>13 Journal of Clinical Oncology. Are you familiar with</p> <p>14 that journal?</p> <p>15 A. I've heard of it.</p> <p>16 Q. Good journal?</p> <p>17 A. I don't know. I've heard of it as a journal.</p> <p>18 I don't really have an opinion about whether it's good</p> <p>19 or not.</p> <p>20 Q. Okay. And on page 14, there is a section they</p> <p>21 described Katie O'Brien as the corresponding author.</p>	<p>1 MR. BISHOP: Objection. Compound.</p> <p>2 THE WITNESS: I don't know if -- I wouldn't say</p> <p>3 I thought they did a good job. I just thought that the</p> <p>4 results of the study suggested to me and provided</p> <p>5 important information in formulating my opinion that</p> <p>6 cosmetic talc does not cause ovarian cancer.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Right.</p> <p>9 Even though, as we talked about, you disagree</p> <p>10 with how the study authors themselves characterized the</p> <p>11 results of the association; true?</p> <p>12 MR. BISHOP: Objection. Asked and answered.</p> <p>13 THE WITNESS: No. I mean, I just read you their</p> <p>14 conclusions, and they said that there was no a</p> <p>15 statistically significant association between the use of</p> <p>16 powder and incidence of ovarian cancer, and that's what</p> <p>17 they concluded.</p> <p>18 BY MR. TISI:</p> <p>19 Q. And then they explained what they meant by that</p> <p>20 in the letter to the editor, the 2021 articles that</p> <p>21 I talked about; true?</p>
Page 115	Page 117
<p>1 And we've talked about that before. That's so that if</p> <p>2 anybody has any questions about the study, why they did</p> <p>3 what they did, when they did what they did, or any</p> <p>4 questions about it, they can reach out to them and ask</p> <p>5 questions, and she gives you her email address; right?</p> <p>6 A. That's correct.</p> <p>7 Q. All right. And these are the same studies --</p> <p>8 these are the same authors that published your -- the</p> <p>9 paper that you relied on as being the best evidence of</p> <p>10 cohort, this pooled study of 2020; correct?</p> <p>11 A. I don't know that I said it's the best evidence.</p> <p>12 I said what I said about it. It was --</p> <p>13 Q. You said it's the most powered. In fact, I'm</p> <p>14 reading it right now. It says -- it says that it is --</p> <p>15 "strongly rebuts the ovarian cancer hypothesis before --</p> <p>16 because it collected more women, had greater statistical</p> <p>17 power, and it followed the women far longer any other --</p> <p>18 far longer a period of time than any other study";</p> <p>19 right?</p> <p>20 You thought that these authors did a really good</p> <p>21 job in their 2020 pooled analysis; correct?</p>	<p>1 MR. BISHOP: Objection. Asked and answered.</p> <p>2 Let's move on.</p> <p>3 THE WITNESS: I did answer that. And that's</p> <p>4 what they said, that there's no statistically</p> <p>5 significant association.</p> <p>6 BY MR. TISI:</p> <p>7 Q. All right. We'll go -- we will -- and they --</p> <p>8 but you relied on these authorization and their results;</p> <p>9 true?</p> <p>10 MR. BISHOP: Objection. I'm sorry. Objection.</p> <p>11 Mischaracterizes.</p> <p>12 THE WITNESS: In formulating my opinion, it was</p> <p>13 one paper that I did consider.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Okay. And they were also the same authors as</p> <p>16 the Gonzalez paper. I think you mentioned that</p> <p>17 Katie O'Brien was the second author in that paper that</p> <p>18 you've relied on in 2019; correct?</p> <p>19 A. The Sister Study published in 2016, I believe</p> <p>20 O'Brien was the second author on that.</p> <p>21 Q. Correct. Let's just attach that for a moment,</p>

<p style="text-align: right;">Page 118</p> <p>1 because we're going to compare it to O'Brien 2024. This 2 is 17.</p> <p>3 (Deposition Exhibit 17 was marked.)</p> <p>4 BY MR. TISI:</p> <p>5 Q. I'm sorry. Gotcha.</p> <p>6 A. It's okay.</p> <p>7 Q. This is the first report of the Sister Study; 8 correct?</p> <p>9 A. You know, I don't know if it's the first report 10 of the actual Sister Study. This is the first --</p> <p>11 Q. The first one you relied on?</p> <p>12 A. The first one I used to formulate an opinion.</p> <p>13 Yes.</p> <p>14 Q. Okay. That's fine.</p> <p>15 Now, O'Brien 2024, you would agree with me, 16 collected more data -- the Sister Study is an ongoing 17 cohort; correct?</p> <p>18 A. That is correct. Yes.</p> <p>19 Q. Okay. So the Gonzalez study had a -- 154 cases 20 and followed women for 6.6 years; correct?</p> <p>21 A. I do believe that women were followed for</p>	<p style="text-align: right;">Page 120</p> <p>1 292."</p> <p>2 Do you see that?</p> <p>3 A. That's correct. Yes.</p> <p>4 Q. Okay. And if you look at the back, it talks 5 about -- I can find it for you, but I will ask you to 6 accept my representation that they were followed for 7 13 -- over 13 years. Okay?</p> <p>8 A. Sound reasonable.</p> <p>9 Q. Okay. So now we have an update on a study that 10 happened -- that -- where you have longer years and more 11 patients; true?</p> <p>12 A. Longer years, more cases. I'd have to look at 13 the actual numbers, but certainly more cases.</p> <p>14 Q. More cases?</p> <p>15 A. Yes.</p> <p>16 Q. And you know it's longer years because at least 17 O'Brien 2020 was 9.6 years, and I'm going to represent 18 this is 13 years out now.</p> <p>19 A. Sure. Longer follow-up time. It's a cohort 20 study. It makes sense.</p> <p>21 Q. And that's what cohort studies do. They follow</p>
<p style="text-align: right;">Page 119</p> <p>1 6.6 years.</p> <p>2 Q. And there were 154 cases; true?</p> <p>3 A. I'm just -- I'm just looking at my report to see 4 if I can see that. It looks like from the methods, 5 154 participants reported a diagnose of ovarian cancer.</p> <p>6 Q. And O'Brien 2020, which is the second paper that 7 we've been talking about today, the second O'Brien 8 paper, it reports that in that study, they looked at 9 additional data, and there were 220 cases in the 10 Sister Study that were followed for 9.6 years; correct?</p> <p>11 A. I would have to look at the article. It sounds 12 reasonable that there would be more cases, given that it 13 was -- that it's an ongoing cohort study.</p> <p>14 Q. Okay. And then in O'Brien 2024, we have now 15 220 cases -- 292 cases, and they were followed for over 16 13 years; correct?</p> <p>17 A. I don't specifically have that memorized. I'm 18 happy to look.</p> <p>19 Q. Well, let's look at table -- on page 3 of the 20 O'Brien 2024. And it says, Sister Studies." And if you 21 look at the bottom, it says, "Ovarian cancer cases,</p>	<p style="text-align: right;">Page 121</p> <p>1 a group of patients over time to see what happens to 2 them. So now the longer the -- particularly for a 3 latent disease like ovarian cancer, you would expect to 4 see more patients the more years -- more cases the more 5 years the study goes on; true?</p> <p>6 A. Yeah. I don't know what you mean by "latent."</p> <p>7 But I -- I know that as women get older, the risk of 8 ovarian cancer goes up.</p> <p>9 Q. Okay. Now, would you agree that in all 10 respects -- putting aside your question about the 11 published analyses in O'Brien 2024 -- the Sister Study 12 data available to the O'Brien investigators when 13 drafting the 2024 article was more robust than it was 14 when the Gonzalez authors accessed the same data for its 15 prior study in Gonzalez?</p> <p>16 A. I don't -- I wouldn't use the word "robust."</p> <p>17 It's more women, more cases, and longer follow-up.</p> <p>18 Q. Okay. And that --</p> <p>19 A. It's the same data.</p> <p>20 Q. And that is -- well, it's not the same data.</p> <p>21 It's the same cohort; right? The data changes.</p>

<p style="text-align: right;">Page 122</p> <p>1 A. And what I mean by that is the same      2 questionnaire given in the beginning, and those women      3 are followed over time.</p> <p>4 Q. Well, we're going to talk about that. It's not      5 unusual in cohort studies for additional questionnaires      6 to be asked of patients as you follow those patients;      7 correct?</p> <p>8 A. That's correct.</p> <p>9 Q. Okay. In fact, as you know from our prior      10 discussion, the Women's Health Initiative and the nurses      11 study asked the questions about talc halfway through the      12 study; correct?</p> <p>13 A. I'd have to look. There were two -- two      14 questionnaires in The Nurses' Health Study, one in      15 Nurses' Health I and one in Nurses' Health II that were      16 administered at different time periods during that --      17 that whole cohort, if you just consider The Nurses'      18 Health Study cohort.</p> <p>19 Q. Right.</p> <p>20 But none of them, other than Sisters, had a      21 question about talc at the time of enrollment; true?</p>	<p style="text-align: right;">Page 124</p> <p>1 answer.</p> <p>2 Q. Okay. And so taking those two options, one is      3 you find out as you look at it that the questionnaire      4 was -- you needed more information from that initial      5 questionnaire. The other way is you may query the data      6 with new information that you may want to explore; true?</p> <p>7 A. Yeah. Or just other things come up in life and      8 you've got a group of people that are engaged and you      9 can ask them questions.</p> <p>10 Q. Okay. So now in O'Brien 2024, they recognized      11 that the initial questionnaire did not capture use of      12 the participants; true?</p> <p>13 A. I don't know. I know a secondary -- a second      14 questionnaire was administered in between 2017 and 2019.      15 I don't know what was involved in creating that      16 questionnaire or in the decision-making to do it.</p> <p>17 So all I'm saying is there's a second      18 questionnaire. I wasn't part of creating that, and      19 I don't know why it was created.</p> <p>20 Q. Okay. Different question, though. Okay?</p> <p>21 If you look at figure 1 in the O'Brien 2024</p>
<p style="text-align: right;">Page 123</p> <p>1 A. I'd have to go look back at when people were      2 enrolled in The Nurses' Health Study.</p> <p>3 Q. Um-hum. But it's not unusual for additional      4 questionnaires to come out as a cohort continues over      5 time; true?</p> <p>6 MR. BISHOP: Objection. Asked and answered.</p> <p>7 THE WITNESS: Yeah. I mean, I said, yeah.</p> <p>8 That's -- that can be fairly common in a cohort study      9 because people are followed over time, and different      10 questions may come up and other questionnaires may be --      11 may be created and administered.</p> <p>12 BY MR. TISI:</p> <p>13 Q. And why would an investigator want to update a      14 questionnaire in a cohort study?</p> <p>15 A. Well, I mean, having performed cohort studies,      16 sometimes you begin the study with maybe a questionnaire      17 that's not fully able to answer the questions that you      18 wanted to, so you perfect that. Or something else comes      19 up and it's a group of people that are being followed      20 that are engaged in research, and it allows for -- for      21 other questions to be answered -- or to be tried to</p>	<p style="text-align: right;">Page 125</p> <p>1 study, the enrollment questionnaire for the Sister Study      2 asked about frequency of use for three years during      3 adolescence between ages 12 and 13, and then in a      4 12-month period before the woman was enrolled; correct?</p> <p>5 A. That's correct.</p> <p>6 Q. Okay. And the follow-up questionnaire after      7 Gonzalez was published, there's more detailed follow-up      8 questions relating to the lifetime use and duration of      9 use of talc; correct?</p> <p>10 A. Yeah. They asked questions about other things      11 in that questionnaire, including douching too, but age,      12 frequency, by decade, why it was used. And, you know,      13 at least for douching, the solution of a douche.</p> <p>14 Q. And the reason why they did that -- we'll go      15 through in this in a moment, but we'll cut out some      16 questions.</p> <p>17 The reason why they did that was because they      18 realized that a woman could actually be a user of talc,      19 answer the initial question correctly, and be      20 characterized improperly as somebody who was a nonuser;      21 true?</p>

<p style="text-align: right;">Page 126</p> <p>1 A. I can't answer that. I wasn't part of the      2 decision-making to create a new questionnaire.      3 Q. Well, they actually say that in the study. You      4 read the study; right?      5 A. I did, yes.      6 Q. Okay. And I will find that in a moment because      7 it's not -- we'll get to that.      8 But they were concerned that the initial      9 questionnaire left out decades of potential talc use;      10 true?      11 A. I --      12 MR. BISHOP: Object -- I'm sorry. Objection.      13 Calls for speculation.      14 THE WITNESS: I would have to see where that's      15 written.      16 BY MR. TISI:      17 Q. Well, let's -- let me ask you this: If you      18 really want to characterize and study talc use, you want      19 to know whether or not a woman ever actually used talc;      20 right?      21 A. That would be an important consideration. Yes.</p>	<p style="text-align: right;">Page 128</p> <p>1 period of time where --      2 Q. Decades?      3 A. -- it wouldn't --      4 Q. Decades?      5 A. -- collect that --      6 Q. Decades?      7 A. -- or we wouldn't know.      8 Q. You wouldn't know because the question wasn't      9 asked, and the concern of the authors was that there      10 might be decades of talc use that wasn't captured in the      11 initial questionnaire; true?      12 MR. BISHOP: Objection. Calls for speculation.      13 THE WITNESS: Yeah, again, I know that there      14 were two questionnaires. Why the second one was      15 created, I could guess. I mean -- but I wasn't involved      16 in creating that.      17 BY MR. TISI:      18 Q. Well, let's talk about that in a moment. Let's      19 talk about that in a moment.      20 When this study came out, you'd actually drafted      21 your report in Carl and Balderrama, which, obviously,</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. It would be -- it would be probably the most      2 critical piece of information. Did they use it; right?      3 A. Did they use it, how often did they use it, and      4 other things too.      5 Q. And the initial questionnaire didn't get to that      6 information, did it?      7 A. The initial questionnaire asked about talc usage      8 in the previous 12 months and whether they used it in      9 between age 13 and 15.      10 Q. And so if there was a 50-year-old woman who      11 entered the study, it would capture use potentially      12 between age 49 and 50 and at 12 and 13 -- 10, 11, 12,      13 and 13 years old; correct?      14 A. That's what that questionnaire would get at.      15 Yes.      16 Q. It would not get at the fact, in that      17 50-year-old woman, that she may have used talc between      18 age 13 and 49; correct?      19 A. 15; right? I mean, isn't --      20 Q. Yes. 13.      21 A. I mean, I'm not -- yeah. So there would be a</p>	<p style="text-align: right;">Page 129</p> <p>1 did not contain any reference to the study whatsoever?      2 A. That's correct. Yes.      3 Q. All right. Now, when did you find out about the      4 this study? And tell me how you found out about this      5 study.      6 A. I don't specifically recall, tell you the truth.      7 Q. You know it was widely -- it was widely reported      8 in the scientific press; true? Even the lay press.      9 A. I don't -- I don't know about "widely."      10 I didn't see it in the lay press.      11 Q. How did you come to -- how did you come to      12 learn -- you were drafting a report. You were in the      13 final stages of finalizing your report. This study is      14 published on May 15th. Your report is due in a couple      15 days.      16 How did you -- you don't -- you don't remember      17 how you -- it came to your attention?      18 A. You know, I don't. I don't specifically know.      19 I don't know if we were talking about finalizing a      20 report and someone said, "Hey, have you seen this?" Or      21 if I was just looking up -- looking up stuff. I really</p>

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<p>1 don't recall.</p> <p>2 I just know that it came out about the time when</p> <p>3 I was finalizing a report, in between April and May.</p> <p>4 Q. Now, this report -- and you notice on page 47,</p> <p>5 this study reports a relative -- excuse me --</p> <p>6 I apologize.</p> <p>7 That this report -- this study reports a hazard</p> <p>8 ratio of 1.82, with a confidence interval of 1.36 to</p> <p>9 2.43; correct?</p> <p>10 A. And where are you referring to?</p> <p>11 MR. BISHOP: Where are you referring to? I'm</p> <p>12 sorry.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Your report.</p> <p>15 MR. BISHOP: What page?</p> <p>16 THE WITNESS: Oh, my report.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Your report. On page -- page 32, third</p> <p>19 paragraph down -- second paragraph down. It says, "1.82</p> <p>20 with 95 confidence interval of 1.36 to 2.43."</p> <p>21 MR. BISHOP: Mischaracterizes the sentence.</p>	<p>1 that the results support a positive association between</p> <p>2 use and intimate care products, including genital talc</p> <p>3 and ovarian cancer; true?</p> <p>4 A. Based on their interpretation of their analysis,</p> <p>5 yes. But, again, this is a thought experiment of four</p> <p>6 different scenarios, and they choose scenario four,</p> <p>7 which is based on a lot of imputations and a lot of</p> <p>8 different assumptions --</p> <p>9 Q. We'll talk about that.</p> <p>10 But that's what they report. They say this</p> <p>11 study supports an association; true?</p> <p>12 A. And -- I wasn't finished, actually.</p> <p>13 What I was about to say is that that is what</p> <p>14 they report. However, their report is based on a lot of</p> <p>15 assumptions which have no founding in creating those</p> <p>16 assumptions.</p> <p>17 Q. We'll talk about that.</p> <p>18 But you have, actually, a chart in your report</p> <p>19 where you list out the various studies; right?</p> <p>20 A. I'm sorry. What?</p> <p>21 Q. You have -- in your report, you have a chart</p>
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<p>1 Go ahead, Doctor.</p> <p>2 THE WITNESS: So what I'm reading in that second</p> <p>3 paragraph is, "Recall bias analyses demonstrated a</p> <p>4 decrease in risk of ovarian cancer with increasing</p> <p>5 proportions of ovarian cancer cases reassigned to never</p> <p>6 use, zero percent, 1.82, hazard ratio 1.36 to 2.43."</p> <p>7 And then if there was 90 percent bias, that</p> <p>8 hazard ratio -- because of differential</p> <p>9 misclassification, that 90 percent bias would reduce the</p> <p>10 hazard ratio to 0.69, which would be actually a</p> <p>11 protective effect of 0.53 to 0.89.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Well, that's not how the authors actually</p> <p>14 interpret their study, that talc has a protective</p> <p>15 effect, does it?</p> <p>16 A. But that's what that table shows.</p> <p>17 Q. Okay. But that's not what -- that's not what it</p> <p>18 said -- they say; right?</p> <p>19 A. I'm just telling you what a hazard ratio means,</p> <p>20 and that is their analysis and that's what it shows.</p> <p>21 Q. They say -- if you look at the conclusion --</p>	<p>1 where you list the studies, and you list the hazard</p> <p>2 ratios or relative risks; correct?</p> <p>3 A. Are you referring to this paper or --</p> <p>4 Q. Your report. In your report, you have a chart.</p> <p>5 A. I do. I have a chart of --</p> <p>6 Q. What page is it on?</p> <p>7 MR. BISHOP: Page 47.</p> <p>8 THE WITNESS: That would be page 47.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Okay. And on that page --</p> <p>11 A. 46 and 47.</p> <p>12 Q. And on page 46 and 47, you list O'Brien 2024 as</p> <p>13 having an association which is characterized as weak,</p> <p>14 the reported association is 1.82 with a confidence</p> <p>15 interval of 1.36 to 2.43; right?</p> <p>16 A. I'm reporting what they reported in the paper.</p> <p>17 Q. Okay.</p> <p>18 A. But what I'm saying is I disagree with the</p> <p>19 interpretation and the analysis --</p> <p>20 Q. Okay.</p> <p>21 A. -- of those results.</p>

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<p>1 Q. Okay. Now, you raised what you call a number of 2 concerns about how they reached that number; right? 3 You used the word "concerns" on page 32. This 4 says "Design, analysis, and interpretation of the 5 results of the study performed by O'Brien, et al., raise 6 a number of concerns"; right? 7 A. That is correct. Yes. 8 Q. And you list them? 9 A. I do. 10 Q. Okay. Now, what did -- I want to know exactly 11 what you did starting May 15th, when this report -- when 12 this study was published -- and the time you finalized 13 your report on May 28th. So this is about 13 days. 14 Okay? 15 I want to know everything you did to investigate 16 your concerns to figure out why they did what they did. 17 Okay? 18 So because -- let me ask you this: Are there 19 any citations in your report for any of the propositions 20 that you -- that you assert on O'Brien 2024, page 31, 21 32, 33, and 34?</p>	<p>1 A. I assume they were. 2 Q. Right. 3 And other people had the opportunity to ask 4 questions of the authors; true? 5 MR. BISHOP: Objection. Calls for speculation. 6 THE WITNESS: Usually a reviewer has the 7 opportunity to reach out to an editor and maybe provide 8 comments to an author, but usually it's reaching out to 9 an editor. 10 BY MR. TISI: 11 Q. Do you know that NIH studies actually have to 12 also be reviewed internally? 13 A. I'm not -- I don't work at the NIH, so I'm not 14 familiar with that. 15 Q. That was not my question. 16 Do you know whether or not studies that are 17 published by NIH authors have to be reviewed internally 18 other -- in addition to being peer reviewed by the 19 journal? 20 MR. BISHOP: Objection. Asked and answered. 21 THE WITNESS: I'm not aware of that.</p>
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<p>1 MR. BISHOP: Objection. 2 BY MR. TISI: 3 Q. Because I don't see any. 4 MR. BISHOP: Objection. Vague and overbroad. 5 BY MR. TISI: 6 Q. Other than citing the article itself. There's 7 nothing on multiple imputation. There's nothing on data 8 correction. There's nothing that you cite here for -- 9 that address the concerns that you raise. 10 A. There were -- 11 MR. BISHOP: Same objection. 12 THE WITNESS: There wouldn't be a reason to cite 13 these things. These concerns would be what I would 14 raise if I was a reviewer of this paper. 15 BY MR. TISI: 16 Q. Okay. But if you were raising these concerns -- 17 first of all, you weren't a reviewer on this paper; 18 correct? 19 A. I was not. 20 Q. Other people were reviewers on this paper; 21 correct?</p>	<p>1 BY MR. TISI: 2 Q. Okay. Thank you. 3 But the way in which an author -- somebody 4 reading a paper might raise -- get questions answered 5 after a paper is published is several ways; right? 6 Number one is you can contact the author; right? 7 MR. BISHOP: Object as compound. 8 THE WITNESS: I mean, one could -- could contact 9 the author. Sure. 10 BY MR. TISI: 11 Q. You didn't do that, did you? 12 A. If I contacted authors about every time I had 13 issues with papers, I'd never be able to write papers 14 myself. 15 Q. Well, this is a little different; right? This 16 is an expert report that you're writing in a talc 17 litigation where you've been paid about \$500,000. And 18 this paper reports a hazard ratio of 1.82. 19 MR. BISHOP: Objection. 20 BY MR. TISI: 21 Q. And you have 13 days to issue your opinions in</p>

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<p>1 this case.</p> <p>2 I want to know: Did you contact or make any</p> <p>3 attempt to contact the authors to find out -- to address</p> <p>4 any of the concerns?</p> <p>5 MR. BISHOP: Objection. Compound. Move to</p> <p>6 strike the comments of Counsel.</p> <p>7 THE WITNESS: I -- I did not contact the authors</p> <p>8 of the paper.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Okay. Did you contact any of your colleagues to</p> <p>11 say, you know, "I have some questions about this paper.</p> <p>12 Could you help me understand what the authors may</p> <p>13 have -- may have been doing here and whether or not this</p> <p>14 is appropriate?"</p> <p>15 Did you do that?</p> <p>16 A. I did not.</p> <p>17 Q. Did you and have you thought about writing a</p> <p>18 letter to the editor like Drs. Harlow and Rothman did</p> <p>19 and say, you know, "I have some concerns about the way</p> <p>20 in which you displayed and analyzed the data" and write</p> <p>21 a formal letter to the editor and ask the authors to</p>	<p>1 this paper.</p> <p>2 Q. Okay.</p> <p>3 A. Because, number one, I wanted to -- I wanted to</p> <p>4 understand it, and it is a very, very complicated paper</p> <p>5 with different scenarios and different assumptions based</p> <p>6 on those scenarios.</p> <p>7 I probably spent about 25 or 30 hours --</p> <p>8 Q. Okay.</p> <p>9 A. -- reviewing it and going over so that I -- that</p> <p>10 I felt comfortable understanding what was done and felt</p> <p>11 comfortable understanding if there were any limitations</p> <p>12 with it. And that's why I bring those concerns up in my</p> <p>13 report.</p> <p>14 Q. Did you talk to any professional colleague about</p> <p>15 what you were going to -- the concerns that you had?</p> <p>16 MR. BISHOP: Objection. Asked and answered.</p> <p>17 THE WITNESS: No, I did not.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. Did you do any research on, for example,</p> <p>20 contradictory data correction?</p> <p>21 A. I think I answered that before. I have</p>
<p>1 actually respond? Have you thought about that?</p> <p>2 A. I think I answered that. Again, if I did that</p> <p>3 for every paper I had concerns about, I would never be</p> <p>4 able to write papers myself.</p> <p>5 Q. And just because you have concerns doesn't mean</p> <p>6 it's not scientific; right?</p> <p>7 MR. BISHOP: Object to form. Vague. Ambiguous.</p> <p>8 THE WITNESS: So I -- this is science.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Um-hum.</p> <p>11 A. I have concerns with the methods in the paper</p> <p>12 and I have concerns with the analysis and I have</p> <p>13 concerns with the conclusions that come from the</p> <p>14 interpretation.</p> <p>15 Q. Were you aware that this study was coming out</p> <p>16 before it came out?</p> <p>17 A. No.</p> <p>18 Q. How much time did you spend researching the</p> <p>19 questions relating to the multiple concerns that you</p> <p>20 raise on page 32 to 34 of your report?</p> <p>21 A. I actually spent a lot of time going through</p>	<p>1 performed data correction and imputations before --</p> <p>2 Q. My bad. I asked the question -- what I mean is</p> <p>3 a different thing.</p> <p>4 In connection with -- and I have this paper in</p> <p>5 front of you, you have 14 days to actually -- 13 days to</p> <p>6 actually finalize your report.</p> <p>7 Did you do any research in connection with your</p> <p>8 preparation of your expert report on contradictory data</p> <p>9 correction in order to express the opinions you're</p> <p>10 putting in this report?</p> <p>11 A. Other than to spend time in reading the report</p> <p>12 and understanding what was -- what was potentially done</p> <p>13 in the data correction and the imputation strategies, no</p> <p>14 further research.</p> <p>15 Q. Did you look at any of the papers -- for</p> <p>16 example, you said you spent 25 hours reading this</p> <p>17 particular study. The authors, for example, cite</p> <p>18 studies for their multiple imputation calculations.</p> <p>19 Did you look at those articles?</p> <p>20 A. Which ones are you referring to?</p> <p>21 Q. I'll ask you in a moment.</p>

<p style="text-align: right;">Page 142</p> <p>1        Did you do anything -- did you look at the 2    footnotes, the articles footnoted on multiple data -- 3    multiple imputation strategies?</p> <p>4    A. No. Again, because in most studies that I do, 5    I have a strategy for multiple imputation which involves 6    usually four or five different -- different strategies.</p> <p>7    So there are lots of different ways to impute data.</p> <p>8    Q. All right.</p> <p>9    A. And I didn't feel like I needed to do any 10   research into that.</p> <p>11   Q. But if you wanted to understand why these 12   authors did what they did and they cited literature, 13   wouldn't you want to understand why they did what they 14   did and the scientific basis for doing that? If you're 15   going to raise concerns and be critical of them.</p> <p>16   A. Yeah. So I understand what you're saying. And 17   I do understand, in general, the imputation strategies 18   that they did perform. One was an adjusted imputation 19   based on covariates, not only covariates that predict an 20   outcome but covariates that predict an exposure.</p> <p>21        And they also perform an imputation that was</p>	<p style="text-align: right;">Page 144</p> <p>1    or featured by the institution if it's an important 2    paper?</p> <p>3    A. Yeah. So, I mean, I've certainly had papers 4    featured. You know, it really depends on why that is. 5    And I've never really -- I've never really questioned as 6    to what the reasons to feature something. There are 7    lots of -- lots of factors go into that.</p> <p>8    Q. Okay. Let's -- have you seen the press release 9    for the -- actually, not the press release. The feature 10   from the journal that published this study? Journal of 11   Clinical Oncology.</p> <p>12   A. I have not, but I'd be happy to look at it.</p> <p>13   Q. Sure. Let's make it Exhibit 18.</p> <p>14        (Deposition Exhibit 18 was marked.)</p> <p>15   BY MR. TISI:</p> <p>16   Q. This is -- for the record, is a feature from the 17   American -- excuse me, the Journal of Clinical Oncology. 18   And it's entitled "Study Finds association between 19   Genital Talc Use and Increased Risk of Ovarian Cancer."</p> <p>20        Do you see that?</p> <p>21   A. I do, yes.</p>
<p style="text-align: right;">Page 143</p> <p>1    sort of on the extreme, and they changed unexposed 2    people to exposed. And that would be one extreme of an 3    imputation strategy.</p> <p>4        So I understand those two strategies. It's not 5    something I need to up. They're strategies I've used in 6    my own research.</p> <p>7    Q. Okay. Did you do any research on sensitivity 8    analysis related to recall bias?</p> <p>9    A. No. And that's -- that's not something I feel 10   like I would need to do, because in doing a sensitivity 11   analysis, all you're doing is -- is reclassifying 12   someone and you're creating nondifferential -- sorry, 13   differential misclassification, which reduces your point 14   estimate towards the null, which is exactly what they 15   did.</p> <p>16   Q. Now, at times, you know, you publish regularly; 17   right?</p> <p>18   A. I have to. Yes.</p> <p>19   Q. Do you -- there are -- do you ever see in your 20   research world that there are times when papers are 21   actually featured papers, either featured by the journal</p>	<p style="text-align: right;">Page 145</p> <p>1    Q. By the way, let me ask you this. You keep 2    characterizing this as a thought experiment; right? 3    You've said that several times today.</p> <p>4        I mean, is there anywhere in the any of the 5    papers that you've seen that addressed this where the 6    authors say, "We're going to engage in a thought 7    experiment"?</p> <p>8    A. No, but they should.</p> <p>9    Q. Oh, they should have -- okay -- in your opinion?</p> <p>10   A. Yes. Absolutely.</p> <p>11   Q. Okay. Next thing, it says, "ASCO perspective." 12   It says, "This study underscores the potential risk 13   associated with intimate care products, particularly 14   genital talc. The evidence adds to a growing body of 15   literature that suggests such products could contribute 16   to an increased risk of ovarian cancer, especially among 17   frequent users and those using these products in their 18   20s and 30s."</p> <p>19        Do you see that?</p> <p>20   A. I do, yes.</p> <p>21   Q. All right. I assume you agree with that?</p>

<p style="text-align: right;">Page 146</p> <p>1 A. Well, it says that it could contribute. It      2 doesn't say that it contributes.</p> <p>3 Q. Well, you say they can't contribute, but you say      4 there's no evidence of an association whatsoever?</p> <p>5 MR. BISHOP: Objection. Mischaracterizes.</p> <p>6 THE WITNESS: What I've said is --</p> <p>7 BY MR. TISI:</p> <p>8 Q. Well, okay. Let's deal with that.</p> <p>9 You say there is no association in your report;      10 right?</p> <p>11 A. I say -- my opinion is there is no causal      12 association --</p> <p>13 Q. Okay.</p> <p>14 A. -- between cosmetic talcum powder products --</p> <p>15 Q. All right. And this --</p> <p>16 A. -- and ovarian cancer.</p> <p>17 Q. So I assume you would disagree with the      18 perspective of the journal that published this article;      19 correct?</p> <p>20 MR. BISHOP: Objection. Vague. Overbroad.</p> <p>21 THE WITNESS: You know, again, I'm not saying</p>	<p style="text-align: right;">Page 148</p> <p>1 Yes.</p> <p>2 Q. Okay. Do you disagree with that?</p> <p>3 A. I disagree that it was positively associated      4 across multiple scenarios. And you'd have to agree on      5 that scenario to agree on whether or not there was a      6 positive association. And I outline this quite -- quite      7 non-vaguely in my report.</p> <p>8 Q. Okay. And there's actually a quote from -- by      9 Dr. O'Brien here on the second page, and I'm going to      10 read it. And, again, this is the same Dr. O'Brien      11 you've been relying on throughout your 2019 and 2024      12 reports; right?</p> <p>13 And she says, "Despite challenges in assessing      14 exposure history and biases inherent in retrospective      15 data, our findings are robust, showing a consistent      16 association between talc, genital use, and ovarian      17 cancer."</p> <p>18 Do you see that?</p> <p>19 A. I do see that.</p> <p>20 MR. BISHOP: Objection. Compound.</p> <p>21</p>
<p style="text-align: right;">Page 147</p> <p>1 that -- I'm not sure what this sentence means.</p> <p>2 It says, "The evidence adds to a growing body of      3 literature that suggests" -- again, not causal --      4 "suggests such products could contribute" -- that's      5 not -- that's -- these are -- this is a very vague      6 statement.</p> <p>7 It suggests that it could be. That's guessing.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Okay. Well, let's take away the guessing. Look      10 at "main takeaway," the bullet point.</p> <p>11 "Genital talc was found to be positive      12 associated with the risk of ovarian cancer across      13 multiple scenarios, even after adjusting for potential      14 reporting biases and misclassification.</p> <p>15 "The association was particularly strong among      16 women who used talc frequently or especially during      17 periods of significant hormonal changes and reproductive      18 activity."</p> <p>19 That's much -- that's a definitive statement;      20 right?</p> <p>21 A. That is much more definitive than the above.</p>	<p style="text-align: right;">Page 149</p> <p>1 BY MR. TISI:</p> <p>2 Q. And she further says, "This study leverages      3 detailed lifetime exposure histories and unique design      4 of the Sister Studies to provide more reliable evidence      5 that supports a potential association between long-term      6 and frequent genital use and ovarian cancer."</p> <p>7 Do you see that?</p> <p>8 A. I do see that.</p> <p>9 Q. Do you disagree with her?</p> <p>10 A. In part, yes. I do disagree with her.</p> <p>11 Q. Okay. And the key findings below say,      12 "Persistent positive association between genital talc      13 use and ovarian cancer with the highest risks observed      14 in frequent and long-term users."</p> <p>15 Do you see that?</p> <p>16 A. I do, yes.</p> <p>17 Q. And you disagree with that?</p> <p>18 A. Again, if we look at the details of the study,      19 there are four different scenarios, and they choose      20 scenario four to look at, which involves imputation      21 and -- mainly imputation of data, and with a lot of</p>

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<p>1 assumptions that really have no founding.</p> <p>2 Q. And you choose to focus on scenario one, where a</p> <p>3 questionnaire was asked prospectively, which could</p> <p>4 exclude decades of use by the -- by the individual</p> <p>5 women; right?</p> <p>6 A. Actually, no. I support -- the table with the</p> <p>7 most evidence is -- is in the supplemental A2 table.</p> <p>8 Q. Okay.</p> <p>9 A. Which is -- and if you look at table A2, the</p> <p>10 first column, that represents women who were</p> <p>11 questioned --</p> <p>12 Q. Um-hum.</p> <p>13 A. -- and followed over time, and there was no</p> <p>14 imputation of data.</p> <p>15 Q. Okay.</p> <p>16 A. And then also relying on table -- on column 3,</p> <p>17 that's fully prospective data, both of incident ovarian</p> <p>18 cancer. And both of those -- both of those groups of</p> <p>19 women show no statistical significance in the risk of</p> <p>20 ovarian cancer.</p> <p>21 Q. Well, let's talk about table A2, ovarian cancer,</p>	<p>1 A. I do, yes.</p> <p>2 Q. Okay. And so there isn't -- there is a -- even</p> <p>3 on this chart, there is a positive association; correct?</p> <p>4 A. There's a positive association which reflects --</p> <p>5 this is -- this is a real world study in recall bias.</p> <p>6 That is second column is labeling people -- women as</p> <p>7 being exposed based on their follow-up questionnaire</p> <p>8 regardless of their initial questionnaire, and that jump</p> <p>9 in a hazard ratio from 1.02 to 2.65 is a clear example</p> <p>10 of what happens with differential misclassification or</p> <p>11 recall bias.</p> <p>12 And, in particular, if you look at the percent</p> <p>13 exposed, the percent exposed in the first column is</p> <p>14 28 percent. That jumps up double to 50 -- 53 percent in</p> <p>15 the --</p> <p>16 Q. That's because -- that's because the --</p> <p>17 MR. BISHOP: Hold on. Let him finish, and then</p> <p>18 you can follow up.</p> <p>19 THE WITNESS: That jumps up to 53 percent in the</p> <p>20 follow-up questionnaire, which was administered in</p> <p>21 between 2017 and 2019, regardless of what they said</p>
Page 151	Page 153
<p>1 288 cases.</p> <p>2 Do you see that? The column of 288 cases on</p> <p>3 table A2.</p> <p>4 A. Yeah. I'm not seeing --</p> <p>5 Q. The second to last from the bottom, above</p> <p>6 uterine cancer.</p> <p>7 Do you see that?</p> <p>8 A. I see. Yes. Sorry.</p> <p>9 Q. It has a 1.02. That's the initial -- that's</p> <p>10 based on the initial questionnaire for 10 to 13 years</p> <p>11 and 12 months before; correct?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. And that would include, potentially,</p> <p>14 decades of talc use; correct?</p> <p>15 A. That's correct.</p> <p>16 Q. Okay. Now, the second -- the second column has</p> <p>17 ovarian cancer, and this would mostly retrospective</p> <p>18 without adjustments of a 2.65 hazard ratio; correct?</p> <p>19 A. That's correct.</p> <p>20 Q. Okay. And the third column has a 1.84.</p> <p>21 Do you see that?</p>	<p>1 before. And then if you look at just prospective cases,</p> <p>2 looking at just people based on their questionnaires and</p> <p>3 then incident -- so the development of ovarian cancer --</p> <p>4 that percent exposed goes back down close to the</p> <p>5 28 percent to 31 percent, with no statistical</p> <p>6 significance there.</p> <p>7 BY MR. TISI:</p> <p>8 Q. So -- but the initial data that you were looking</p> <p>9 at excludes women with decades of data, potentially use</p> <p>10 data; true?</p> <p>11 A. And then in order to --</p> <p>12 Q. You got to answer my question. Is that yes or</p> <p>13 no?</p> <p>14 A. Yes. Based on my interpretation --</p> <p>15 Q. All right.</p> <p>16 A. -- of this, but there's no --</p> <p>17 MR. BISHOP: Let him finish --</p> <p>18 MR. TISI: No.</p> <p>19 (Indistinguishable simultaneous speaking;</p> <p>20 reporter admonishment.)</p> <p>21 MR. TISI: If it's a yes-or-no answer --</p>

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1	MS. PARFITT: Chris --	1 BY MR. TISI:
2	MR. TISI: -- it's yes or no.	2 Q. Now, this is a feature by the NIH.
3	MR. BISHOP: He can put his answer. You can	3 Do you see the NIH logo there?
4	move to strike. That's how it works.	4 A. I do, yes.
5	MR. TISI: Okay.	5 Q. Okay. And it says -- underneath the headline,
6	MR. BISHOP: So finish your answer, please.	6 it says, "New study by NIEHS scientists provide
7	MR. TISI: We're going to move on. Next	7 compelling evidence that genital talc use is associated
8	question.	8 with increased risk of ovarian cancer."
9	MR. BISHOP: Did you finish your answer?	9 See that?
10	THE WITNESS: What I was going to --	10 A. Yes.
11	BY MR. TISI:	11 MR. TISI: That's somewhat concerning.
12	Q. I'm going to ask you all about this chart.	12 THE WITNESS: Yeah. That's weird.
13	I promise you I will. Okay? And I'm going to give you	13 MR. TISI: Do you want to take a break and we
14	full opportunity to ask the question.	14 can -- we'll go off the record.
15	The initial -- the initial question I asked you	15 (Off the record.)
16	was: The initial questionnaire excluded potential	16 BY MR. TISI:
17	decades of data -- yes or no -- about use.	17 Q. Let's go back on the record. Go back to
18	A. So this is where it's difficult for me to	18 Exhibit Number 19. There's a quote by Dr. O'Brien
19	interpret this -- this aspect of it, because if you look	19 again. Oh, it says, "Despite challenges in assessing
20	at the title of the table, it says, "Uncorrected,	20 exposure history and biases inherent in retrospective
21	unadjusted hazard ratios for an association between	21 data, our findings are robust, showing a consistent
	Page 155	Page 157
1	intimate care products, hormone-related cancers on the	1 association between talc use and ovarian cancer."
2	basis of use reported enrollment or on the fourth	2 That's the same quote we read before; correct?
3	detailed follow-up use."	3 A. That's correct.
4	And so it could be an "or" there. And -- but in	4 Q. Okay. And you disagreed with that; right?
5	formulating an opinion on this table, moving forward to	5 A. Again it depends on which scenario you're
6	the third column where there's a similar percent exposed	6 looking at. And, again, they're talking about the
7	and a nonstatistical -- a nonstatistically significant	7 results of scenario four, which has a lot of assumptions
8	hazard ratio there, that's fully prospective.	8 that one would have to agree with because there's
9	And so that's getting at -- that's getting at	9 changing of data and imputation of data. And when we
10	the potential loss of data for people that have not been	10 look at the data itself, it doesn't show that
11	followed over time.	11 association.
12	BY MR. TISI:	12 Q. Next page. It says, "Key findings persist" --
13	Q. Okay. Move to strike. Doesn't answer my	13 on the -- from the NIH.
14	question.	14 "Key findings of the study are persistent
15	This was also featured -- this article was also	15 positive association between genital talc use and
16	featured on the NIH -- by the NIH as well.	16 ovarian cancer with the strongest associations observed
17	Do you know that?	17 with frequent and long-term users and for use during
18	A. No.	18 reproductive years."
19	Q. Okay. I'm going to show you what I'd like to	19 Correct?
20	have marked as Exhibit Number 19.	20 A. That's what it says. Yes.
21	(Deposition Exhibit 19 was marked.)	21 Q. And then if you look, there's pictures of the

40 (Pages 154 - 157)

<p style="text-align: right;">Page 158</p> <p>1 Dr. Sandler and Dr. O'Brien. It says -- Dr. Sandler and      2 O'Brien write, "There is no medical reason to use these      3 products. For women are using these products, they may      4 want to reduce their frequency of use, look for      5 alternatives, or talk to their doctor about the      6 concerns."</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. Do you have any feelings about that?</p> <p>10 A. I mean --</p> <p>11 MR. BISHOP: Objection. I'm sorry. Objection.</p> <p>12 THE WITNESS: That --</p> <p>13 BY MR. TISI:</p> <p>14 Q. Do you have any opinions about that, whether      15 women should be using talc in light of this study?</p> <p>16 A. I have no opinion about that. Dr. O'Brien is      17 not a medical doctor.</p> <p>18 Q. Okay.</p> <p>19 MR. TISI: We'll take a quick break.</p> <p>20 (Recess taken.)</p> <p>21 MR. TISI: Back on the record.</p>	<p style="text-align: right;">Page 160</p> <p>1 would have caught that?</p> <p>2 MR. BISHOP: Objection. Calls for speculation.</p> <p>3 THE WITNESS: I don't know.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. Would it be fair to say that there are      6 few things in science more egregious than starting an      7 experiment and saying, "I know where I'm going to go and      8 I'm going to manipulate the data to get there"?</p> <p>9 MR. BISHOP: Objection. Mischaracterizes.</p> <p>10 THE WITNESS: I didn't say that that happened.</p> <p>11 I said that it raises a concern that it happened because      12 of the imputation strategies and the strategy and the --      13 so when you do imputation strategies, it's really to      14 sort of confirm a -- an analysis where there's missing      15 data.</p> <p>16 BY MR. TISI:</p> <p>17 Q. We're going to talk about that. I'm simply      18 asking you: Raising a concern that a researcher,      19 particularly of this caliber, had manipulated data to      20 get to a predetermined result is a pretty serious thing      21 if it -- pretty serious charge; right? Or a pretty</p>
<p style="text-align: right;">Page 159</p> <p>1 BY MR. TISI:</p> <p>2 Q. All right. So we took a break because of some      3 disturbance outside, so I appreciate your taking a      4 break.</p> <p>5 Let's talk about the paper itself and your      6 criticisms. I jumped ahead a little bit. So let's      7 go -- double back and see if we can cover some things      8 that I intended to do.</p> <p>9 On page 34 of your report, if you would go to      10 that -- we talked about this briefly before. You --</p> <p>11 I was curious about the phrase, and we talked about      12 "data manipulation in order to demonstrate a      13 predetermined result."</p> <p>14 Do you see that?</p> <p>15 A. I do.</p> <p>16 Q. Okay. Do you feel that in any way that was an      17 unfortunate choice of words by you?</p> <p>18 A. No. It raises a concern that there was a      19 predetermined result and data manipulation to get there.</p> <p>20 Q. Okay. If that were true, don't you think that      21 the various peer reviewers and the journal and the NIH</p>	<p style="text-align: right;">Page 161</p> <p>1 serious thing to raise; true?</p> <p>2 MR. BISHOP: Objection. Compound.</p> <p>3 THE WITNESS: It raises a concern for me.</p> <p>4 BY MR. TISI:</p> <p>5 Q. All right. And it would be particularly      6 egregious since these authors are in charge of a large      7 cohort study for the National Institutes of Health;      8 right? I mean, I will represent to you that      9 Dale Sandler is principal investigator for the      10 Sister Study, which is an important cohort; true?</p> <p>11 MR. BISHOP: Objection. Compound.</p> <p>12 THE WITNESS: I'm not aware who the PI of the      13 Sister Study is --</p> <p>14 BY MR. TISI:</p> <p>15 Q. Well, I will represent to you that Dale Sandler      16 was the principal investigator and head of epidemiology      17 at the NEIHS and is the head -- the principal      18 investigator for the Sister Study.</p> <p>19 If that were true -- and I represent to you that      20 it is -- that it would be a pretty serious thing for a      21 pretty important person in charge of a pretty important</p>

<p>1 study; true?</p> <p>2 MR. BISHOP: Objection. Vague. Ambiguous.</p> <p>3 Overbroad.</p> <p>4 THE WITNESS: I'm -- I'm going to stand by my</p> <p>5 concern.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Okay.</p> <p>8 A. Because there's significant imputation and a lot</p> <p>9 of assumptions to get to the conclusion that the 1.82</p> <p>10 estimate would be the estimate to choose to then perform</p> <p>11 a recall bias sensitivity analysis.</p> <p>12 Q. Do you know what -- have you ever had heard the</p> <p>13 phrase "put your money where your mouth is"? You've</p> <p>14 heard that phrase?</p> <p>15 A. I have. Yes.</p> <p>16 Q. Okay. If you thought there might be scientific</p> <p>17 misconduct in the conduct of an important study like</p> <p>18 Sister Study, would you feel duty-bound to either</p> <p>19 investigate or report it?</p> <p>20 A. So I never said there was scientific misconduct.</p> <p>21 I said data manipulation which is an imputation</p>	<p>Page 162</p> <p>1 I said before, had I been a reviewer of this study,</p> <p>2 I would have raised those concerns.</p> <p>3 Q. Okay. So other than litigation experts who have</p> <p>4 been paid hundreds of thousands of dollars to testify on</p> <p>5 behalf of J&amp;J, do you know any scientists independent</p> <p>6 who have raised the concerns that this was data</p> <p>7 manipulation to reach a predetermined result? Anybody</p> <p>8 who has raised your concern here.</p> <p>9 A. I haven't spoken to anyone about it. What I'm</p> <p>10 telling you --</p> <p>11 Q. Have you seen it? Have you seen it in the</p> <p>12 literature? Has anything that has happened since this</p> <p>13 study has been published that anybody has said what</p> <p>14 you've said in your litigation report?</p> <p>15 A. The study is relatively new and it does raise a</p> <p>16 concern to choose that scenario.</p> <p>17 Q. But has anybody outside of litigation, to your</p> <p>18 knowledge, raised that concern?</p> <p>19 A. Not that I'm aware of.</p> <p>20 Q. Okay. Do you have any intent to bring your</p> <p>21 concern to the NIH, to the ASCO journal authors, or</p>
<p>Page 163</p> <p>1 strategy. That's data manipulation.</p> <p>2 Q. To reach a predetermined result. That's --</p> <p>3 that's the part that would be inappropriate,</p> <p>4 scientifically; correct?</p> <p>5 A. If that's what you're reporting. And --</p> <p>6 Q. Okay. So my question is: If you had a concern</p> <p>7 about that, don't you think that would be important to</p> <p>8 either ask for an investigation or to try to seek out</p> <p>9 the answers to the concerns you raise?</p> <p>10 MR. BISHOP: Objection. I'm sorry. Vague.</p> <p>11 Ambiguous. Overbroad.</p> <p>12 THE WITNESS: So the answers are in the paper</p> <p>13 themselves --</p> <p>14 BY MR. TISI:</p> <p>15 Q. Okay.</p> <p>16 A. -- themselves.</p> <p>17 And the reason is they're -- they're using</p> <p>18 scenario four as their end-all result.</p> <p>19 Q. Okay.</p> <p>20 A. And one would have to assume or agree with all</p> <p>21 the assumptions that go into scenario four. And as</p>	<p>Page 165</p> <p>1 anybody else?</p> <p>2 A. No.</p> <p>3 Q. Do you have any intent to ask for an</p> <p>4 investigation?</p> <p>5 A. Again, there would be no reason to be -- to</p> <p>6 investigate. The reason is it's a concern of mine to</p> <p>7 choose that scenario as the hazard ratio to then perform</p> <p>8 the recall bias sensitivity analysis, when that scenario</p> <p>9 is based on a lot of different assumptions and -- and</p> <p>10 end imputation strategies that may or may not make</p> <p>11 sense.</p> <p>12 Q. Well, I've now shown you the exhibit which is</p> <p>13 the NIH feature for the world to see about the NIH's</p> <p>14 view about O'Brien 2024 provides compelling evidence</p> <p>15 that general talc use is associated with ovarian cancer,</p> <p>16 and the data supports a persistent positive association.</p> <p>17 Do you have any intent to contact the NIH and</p> <p>18 say, you really ought to take that down?</p> <p>19 A. Not to this point, I haven't thought about that.</p> <p>20 Q. Do you have any evidence -- just to be</p> <p>21 100 percent sure clear -- that the authors of O'Brien</p>

<p style="text-align: right;">Page 166</p> <p>1 2024 intentionally manipulated data to reach a      2 conclusion that talking was associated with ovarian      3 cancer?</p> <p>4 MR. BISHOP: Objection. Asked and answered.</p> <p>5 THE WITNESS: So, again, I never said I had      6 evidence. I said it raises a concern.</p> <p>7 BY MR. TISI:</p> <p>8 Q. So you do not have evidence?</p> <p>9 A. I said I have a concern, and I never said I had      10 evidence.</p> <p>11 Q. I -- okay.</p> <p>12 So that was just a thought experiment by you?</p> <p>13 MR. BISHOP: Objection. Argumentative.</p> <p>14 THE WITNESS: No, no. I just -- it's a concern      15 because there are other scenarios that use the actual      16 data.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Okay.</p> <p>19 A. And scenario four is a thought experiment, and      20 that is the result they choose, which is inconsistent      21 with the real data.</p>	<p style="text-align: right;">Page 168</p> <p>1 result.</p> <p>2 Q. You have a department of biostatistics at      3 Johns Hopkins, don't you?</p> <p>4 A. We do, yes.</p> <p>5 Q. Do you know who the chair of that department is?</p> <p>6 A. It used to be Marie Dina West. I don't know who      7 the chair is now.</p> <p>8 Q. Do you know who Liz Stuart is?</p> <p>9 A. No.</p> <p>10 Q. Dr. Stuart.</p> <p>11 Do you know whether or not Dr. Stuart, the chair      12 of the department, has written about when you use      13 multiple imputation strategies?</p> <p>14 A. I'm not familiar with her writing on that. I      15 know when we use them.</p> <p>16 Q. Are you a professor of biostatistics?</p> <p>17 A. I'm not.</p> <p>18 Q. Have you spoken to any biostatistician in your      19 department about when to use multiple imputation      20 strategies?</p> <p>21 A. I have, from time to time. We have a</p>
<p style="text-align: right;">Page 167</p> <p>1 Q. But you're musing about whether or not they used      2 a pre -- a methodology that would reach a predetermined      3 outcome was just a musing by you in your report, this      4 concern that you raise?</p> <p>5 MR. BISHOP: Object to the form.</p> <p>6 Mischaracterizes.</p> <p>7 THE WITNESS: No. That's not what I said. What      8 I'm saying is -- and I'll give you a clear example.</p> <p>9 When I've performed studies, cohort studies with      10 missing data and we use imputation strategies to fill in      11 the missing data and the data doesn't make sense after      12 you've imputed things -- meaning there's discord between      13 your real data and that's been imputed, that raises      14 concerns.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay.</p> <p>17 A. And --</p> <p>18 Q. Well, good --</p> <p>19 A. And that is the concern that I have, that the      20 imputed data based on the assumptions that are brought      21 forth in the paper produce a dramatically different</p>	<p style="text-align: right;">Page 169</p> <p>1 biostatistician that works with our group. And from      2 time to time I've talked about different strategies for      3 imputation and when to use it.</p> <p>4 Q. Did you ask -- in connection with this study,      5 did you go to a biostatistician in your department and      6 ask -- in your school and ask them, you know, "They're      7 using this in a way that I have not seen used before.      8 Can you give me your thoughts about that?"</p> <p>9 A. So I never said this is -- they're using this in      10 a way that I've never seen before.</p> <p>11 Q. Okay.</p> <p>12 A. I said I'm familiar with their strategies of      13 imputation, and I'm familiar with data correction,      14 because all that is doing is just reassigning exposure      15 to non-exposure or non-exposure to exposure. I'm      16 completely familiar with that.</p> <p>17 Q. Okay. You --</p> <p>18 A. My issue is choosing the strategy that's based      19 on a lot of different imputations and data correction      20 and using that strategy as the point estimate for the      21 recall bias --</p>

<p style="text-align: right;">Page 170</p> <p>1 Q. So you don't -- I'm sorry. Were you finished?</p> <p>2 A. -- for the recall bias analysis.</p> <p>3 Q. So you have no problem with using multiple</p> <p>4 imputation strategies to account for missing data;</p> <p>5 correct?</p> <p>6 A. I didn't say that either. I think multiple</p> <p>7 imputation strategies are used when there is a certain</p> <p>8 percentage of missing data to try to account --</p> <p>9 Q. What percent?</p> <p>10 A. I mean, it depends. Usually if there's around</p> <p>11 10 percent, you might try to. But it's going to depend</p> <p>12 on the factor.</p> <p>13 One of the things that I study is decline in</p> <p>14 lung function. And if I have somebody who's followed</p> <p>15 for ten years and they -- they're supposed to get lung</p> <p>16 function every quarter for ten years but they're missing</p> <p>17 a couple in between, you can pretty finely tune the</p> <p>18 imputation of that lung function based on the two -- the</p> <p>19 two that flank that.</p> <p>20 Now, that's an easier imputation strategy than</p> <p>21 something like this where they're using covariates to</p>	<p style="text-align: right;">Page 172</p> <p>1 frequentist when it comes to your approach to analyzing</p> <p>2 data?</p> <p>3 A. I certainly have used frequency analyses before,</p> <p>4 and I certainly have used Bayesian analyses before.</p> <p>5 Q. Do you know how bootstrapping is using in</p> <p>6 multiple imputation strategies?</p> <p>7 A. I do, yes.</p> <p>8 Q. Do you know what multiple imputation with</p> <p>9 chained equations, or MICE, is?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. What is it?</p> <p>12 A. It's a way to use other variables to use as</p> <p>13 covariates to predict usually an outcome if you're</p> <p>14 missing an outcome data.</p> <p>15 Q. Do you know -- I'm sorry. Didn't mean --</p> <p>16 A. It appears that in this paper, the investigators</p> <p>17 also used this to predict exposure too. And, that,</p> <p>18 I have a little bit of a difficulty in grasping whether</p> <p>19 or not that's a concept I agree with.</p> <p>20 Q. Okay. Do you know what the Benjamini-Hochberg</p> <p>21 procedure control for, and how does it differ from the</p>
<p style="text-align: right;">Page 171</p> <p>1 predict not only an outcome but predict an exposure, and</p> <p>2 that's complicated.</p> <p>3 Q. It's complicated, and it would require -- well,</p> <p>4 first of all, who is the biostatistician that you use</p> <p>5 that you referred to that would be -- you said you would</p> <p>6 consult with on multiple imputation strategies?</p> <p>7 A. So there's a biostatistician named Kevin Psoter</p> <p>8 who we've worked with over the course of time.</p> <p>9 Q. Have you spoken to Kevin Psoter about this the</p> <p>10 paper?</p> <p>11 A. No.</p> <p>12 Q. Have you spoken to any bio- -- and, again, you</p> <p>13 don't -- are you an expert in biostatistics?</p> <p>14 A. I have expertise in epidemiology, and I also</p> <p>15 have expertise in the analysis of longitudinal data.</p> <p>16 Q. Just a different question.</p> <p>17 Do you consider yourself to be an expert in</p> <p>18 biostatistics?</p> <p>19 A. I think part of my -- my expertise in</p> <p>20 epidemiology does include biostatistics.</p> <p>21 Q. Do you consider yourself a Bayesian or</p>	<p style="text-align: right;">Page 173</p> <p>1 Bonferroni correction?</p> <p>2 A. I know what a Bonferroni correction is. It's</p> <p>3 usually a correction for multiple analyses. The other</p> <p>4 term, I'm not familiar with.</p> <p>5 Q. If I could kind of synthesize all of the</p> <p>6 concerns that you raise in your report, you have</p> <p>7 concerns with O'Brien's contradictory data correction</p> <p>8 methodology; correct?</p> <p>9 A. I have concerns that the results contradict</p> <p>10 themselves depending on the level of imputation and --</p> <p>11 and what analyses were performed.</p> <p>12 Q. Do you have -- and you have concerns about the</p> <p>13 missing data imputation, which you criticize; correct?</p> <p>14 A. So, again, it's a strategy to try to get at</p> <p>15 missing exposure and missing outcome data. Usually when</p> <p>16 you input -- impute data, it's to gather more</p> <p>17 covariates, and it's not that standard to certainly</p> <p>18 impute exposure, because you're just guessing.</p> <p>19 Q. Okay. So -- and just one other question.</p> <p>20 Do you have concerns about sensitivity analysis</p> <p>21 relating to recall bias methodology?</p>

<p style="text-align: right;">Page 174</p> <p>1 A. No. I think that's -- that's done very, very      2 well.</p> <p>3 Q. Okay. Now, we -- I asked you whether or not      4 you've done any research on these issues, the      5 methodology issue between the time you received the      6 O'Brien report and the time you issued your report, and      7 you said you didn't have to.</p> <p>8 You didn't; right?</p> <p>9 A. I feel like I needed to do that because I have      10 performed imputation strategies similar to this in the      11 past using longitudinal cohort data.</p> <p>12 Q. Okay. And I understand that you did not consult      13 with a biostatistician -- including biostatisticians in      14 your own department; correct?</p> <p>15 MR. BISHOP: Objection. Asked and answered.</p> <p>16 THE WITNESS: I did not.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Okay. And in the 13 days between the time you      19 got this report of this study, Exhibit Number 3, and the      20 time you issued your report, did you have occasion to      21 speak to J&amp;J's lawyers?</p>	<p style="text-align: right;">Page 176</p> <p>1 other experts about what was being said about O'Brien      2 2024?</p> <p>3 A. They did not.</p> <p>4 Q. Have you spoken to any J&amp;J litigation      5 consultants or experts relating to O'Brien 2024?</p> <p>6 A. Okay. Can you ask that again?</p> <p>7 Q. Yeah.</p> <p>8 Have you spoken to any J&amp;J litigation      9 consultants or experts relating to O'Brien 2024?</p> <p>10 A. Not that I can think of.</p> <p>11 Q. Now, you know, so you had -- let's go back to      12 the -- you had 13 days to draft this -- these -- and      13 address your concerns. They are concerns. They're not      14 really -- you don't hold opinions other than you were      15 raising concerns; right?</p> <p>16 MR. BISHOP: Objection. Vague. Overbroad.</p> <p>17 Mischaracterizes.</p> <p>18 THE WITNESS: I mean, I think I say that in my      19 report.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Okay.</p>
<p style="text-align: right;">Page 175</p> <p>1 A. In -- in finalizing my report, we did have a      2 couple meetings. Yes.</p> <p>3 Q. Did you have meetings where the issues relating      4 to O'Brien 2024 were discussed?</p> <p>5 A. What do you mean by "issues"?</p> <p>6 Q. Did you discuss with them issues relating to      7 your concerns about 2024?</p> <p>8 A. I showed you what -- I showed them what I wrote      9 down in my report.</p> <p>10 Q. Okay. Did they interact with you on that?</p> <p>11 MR. BISHOP: Objection. Vague. Overbroad.</p> <p>12 THE WITNESS: Well, we had a meeting to discuss      13 it, and we talked about my -- my opinions based on the      14 manuscript and also what I had written in the report.</p> <p>15 BY MR. TISI:</p> <p>16 Q. What lawyers did you speak to?</p> <p>17 A. Ms. Davidson and Mr. Bishop.</p> <p>18 Q. Okay. And did they provide you with any      19 information that you did not have? In other words, did      20 they represent to you what other experts were saying?</p> <p>21 Did they provide you with an expert report from any</p>	<p style="text-align: right;">Page 177</p> <p>1 A. I -- the design analysis, interpretation results      2 performed by O'Brien all raise a number of concerns.</p> <p>3 Q. Right.</p> <p>4 A. And then I outline that in the report.</p> <p>5 Q. Right.</p> <p>6 And raising concerns is not the same thing as      7 having an opinion to a reasonable degree of scientific      8 certainty; true?</p> <p>9 MR. BISHOP: Objection. Argumentative      10 mischaracterizes.</p> <p>11 THE WITNESS: So that's just a statement in my      12 report and then each paragraph afterwards talks about my      13 opinion.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Well, you -- several times, you just raise      16 questions; right? I mean, you just raise -- I mean,      17 we'll talk about them. But you just raise questions,      18 why, for example, they didn't include the BRCA analysis;      19 correct?</p> <p>20 A. That's correct.</p> <p>21 Q. All right. Raising the question is not anything</p>

<p style="text-align: right;">Page 178</p> <p>1 more than raising a question. I can raise a question as      2 to whether or not it's hot outside or not looking out      3 the window, but if I'm not outside, I don't know.      4 I don't have an opinion on that.</p> <p>5 My question is: Do you have an opinion that you      6 hold to a reasonable degree of medical and scientific      7 certainty relating to the concerns that you have?</p> <p>8 MR. BISHOP: Objection. I'm sorry. Vague.</p> <p>9 BY MR. TISI:</p> <p>10 Q. And questions you raise.</p> <p>11 MR. BISHOP: Vague and overbroad.</p> <p>12 THE WITNESS: So the questions that I raised,      13 I raised them and I will stand by them. My biggest      14 concern with this paper is the choice in scenario to --      15 to use as their final result because -- because of --      16 because of what is presented.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Okay.</p> <p>19 A. And the strategy to get there.</p> <p>20 Q. And you don't know -- and you don't know why      21 they did what they did; right? You didn't call them.</p>	<p style="text-align: right;">Page 180</p> <p>1 that.</p> <p>2 THE WITNESS: And so, number one, that is a red      3 flag. And, number two, the -- the choice of      4 scenario four, again, I have big concerns with      5 because -- because there are imputation techniques that      6 get you there, and when you use scenario one, or in      7 table A2, the people who are followed forward, those      8 results are dramatically different.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Now, you've called into question the integrity      11 of the authors here by raising these concerns.</p> <p>12 Do you think it's also fair for an objective      13 scientist or judge or a juror to question whether you      14 are objecting -- objectively looking at O'Brien 2024 in      15 light of your accepting 4- or \$500,000 to look at this      16 case and having already committed yourself to the      17 position that talc doesn't cause ovarian cancer?</p> <p>18 MR. BISHOP: Object to form.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Do you think that's reasonable to raise that      21 question?</p>
<p style="text-align: right;">Page 179</p> <p>1 You didn't ask them. You haven't -- and you don't      2 intend to.</p> <p>3 Other than reading the paper, you have no      4 additional information that would shed light on your      5 concern?</p> <p>6 MR. BISHOP: Objection. Vague. Overbroad.      7 Calls for speculation.</p> <p>8 THE WITNESS: I had not planned on calling any      9 of the authors. But in -- in the interpretation of the      10 data from this study, it is unclear to me as to why,      11 number one, there's a difference in when data is      12 imputed. That's usually a red flag when there's a      13 difference --</p> <p>14 BY MR. TISI:</p> <p>15 Q. What are we talking about --</p> <p>16 MR. BISHOP: Let him finish.</p> <p>17 MR. TISI: No. I do want to -- I am,      18 actually --</p> <p>19 MR. BISHOP: He can finish his answer.</p> <p>20 MR. TISI: I understand. But I am going to ask      21 you about that -- I promise you, I will ask you about</p>	<p style="text-align: right;">Page 181</p> <p>1 MR. BISHOP: Object to form. Argumentative.      2 Move to strike comments of Counsel.</p> <p>3 THE WITNESS: So my -- my job is to be as      4 objective as possible, and my opinion in 2019 could      5 certainly change. My opinion two years from now could      6 certainly change and I -- my job is to be as objective      7 as possible. This paper does not change my opinion.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Okay.</p> <p>10 A. And the reason is because using scenario one,      11 comparing it to the extreme where recall bias is into      12 that and then looking prospectively, this is -- this is      13 like three different studies in itself. It's a cohort      14 study, there's a recall, there's a -- sort of a case      15 control kind of recall thing, and then there's a      16 longitudinal component of just prospective.</p> <p>17 So we learn a lot from this study from a study      18 design and epidemiologic standpoint.</p> <p>19 Q. You call O'Brien's work a thought experiment.</p> <p>20 Do you think that your concerns outlined for      21 four pages in your report could also be considered a</p>

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<p>1 thought experiment?</p> <p>2 A. I don't.</p> <p>3 Q. Okay.</p> <p>4 A. Absolutely not.</p> <p>5 Q. Let's talk about some of your concerns.</p> <p>6 On page 33 of your report, you say here -- one,</p> <p>7 two, three, four -- page 33 -- you said here, "Every</p> <p>8 scenario in table 2 involves at least some imputation.</p> <p>9 Because scenario three was intended to merely illustrate</p> <p>10 an extreme, I focus here on scenario four. This study</p> <p>11 does not provide any explanation to justify the</p> <p>12 assumptions/selections of covariates used in</p> <p>13 scenario four, and this unquestionably limits the</p> <p>14 validity of the study."</p> <p>15 Do you see that?</p> <p>16 A. I do, yes.</p> <p>17 Q. Okay. Putting aside the fact this article</p> <p>18 passed peer review, did you seek to investigate why --</p> <p>19 the explanation for why they chose scenario four?</p> <p>20 MR. BISHOP: Objection. Asked and answered.</p> <p>21 THE WITNESS: Well, I said to you earlier, I did</p>	<p>1 I don't know exactly what was done. It's not</p> <p>2 described --</p> <p>3 BY MR. TISI:</p> <p>4 Q. So --</p> <p>5 A. -- and so my opinion is I have a concern about</p> <p>6 it because the imputed data is very different than the</p> <p>7 data by itself that's not imputed.</p> <p>8 Q. My question is very specific, so I'm going to</p> <p>9 ask you to answer my question.</p> <p>10 Do you have any opinion, to a reasonable degree</p> <p>11 of scientific certainty, that the covariates used in</p> <p>12 scenario four were not scientifically justified? And if</p> <p>13 you don't know, you don't know.</p> <p>14 A. I don't have an opinion about that.</p> <p>15 Q. Okay. On page 33, you also say, "Of note, there</p> <p>16 is no reported analysis comparing those with missing</p> <p>17 data to those without missing data. It would be</p> <p>18 important to know if these -- if those with missing data</p> <p>19 are different from those without missing data. It's</p> <p>20 impossible to understand the methods to determine how</p> <p>21 covariates were selected to perform the imputation,</p>
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<p>1 not contact any of the authors about that.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Do you have anything further to add that's</p> <p>4 beyond raising concerns?</p> <p>5 A. That it's unclear to me as to why scenario four</p> <p>6 was chosen as the point estimate and confidence interval</p> <p>7 for the final results of this paper.</p> <p>8 Q. Do you have any opinion to a reasonable degree</p> <p>9 of scientific certainty that the covariates used in</p> <p>10 scenario four were not scientifically justified?</p> <p>11 A. Can you ask that again? I'm not sure I</p> <p>12 understand.</p> <p>13 Q. Do you have any opinion to a reasonable degree</p> <p>14 of scientific certainty that the covariates used in</p> <p>15 scenario four were not scientifically justified?</p> <p>16 A. The covariates that were used and the analysis</p> <p>17 and plan -- like, I don't know the code for it. So --</p> <p>18 Q. Okay.</p> <p>19 A. So you don't have an opinion on that?</p> <p>20 MR. BISHOP: Let him finish his answer.</p> <p>21 THE WITNESS: So I couldn't repeat this because</p>	<p>1 which seems particularly problematic."</p> <p>2 Did I read that correctly?</p> <p>3 A. Yes.</p> <p>4 Q. Did you -- and we know you didn't contact the</p> <p>5 authors.</p> <p>6 If it's impossible to understand the methods</p> <p>7 that pass peer reviewed, I assume you can't form another</p> <p>8 opinion on that; correct?</p> <p>9 A. What I have an opinion on is that you can't</p> <p>10 understand the methods --</p> <p>11 Q. Right.</p> <p>12 A. -- because they're not fully described.</p> <p>13 Q. Right. And --</p> <p>14 A. And usually the first step in performing an</p> <p>15 analysis of missing data is to really compare people</p> <p>16 with a full dataset, people with some missing data, and</p> <p>17 then people with a lot of missing data. And if those</p> <p>18 groups are different, then you have a problem. And that</p> <p>19 wasn't described. And that's the first step in an</p> <p>20 imputation analysis.</p> <p>21 Q. Okay. But my question is: Given the fact that</p>

<p style="text-align: right;">Page 186</p> <p>1 you have some gaps in your understanding of the methods      2 and haven't reached out to fill those gaps, do you have      3 any opinions that you hold to a reasonable degree of      4 scientific certainty that the covariates selected were      5 incorrect?</p> <p>6 A. Which covariates are you talking about?</p> <p>7 Q. The ones used for the imputation strategy.</p> <p>8 A. Which imputation strategy?</p> <p>9 Q. Well, the ones referred to on page 33 that we      10 said it would be important to know if those missing data      11 were different for those without missing data. You      12 raised concerns.</p> <p>13 And my question is: Since you don't know the      14 answers to those questions, you can't really formulate      15 an opinion; true?</p> <p>16 MR. BISHOP: Objection. Vague and ambiguous.      17 Overbroad.</p> <p>18 THE WITNESS: Yeah, no. Not necessarily. I do      19 have an opinion that it's a problem.</p> <p>20 BY MR. TISI:</p> <p>21 Q. It's a problem, but you just don't know because</p>	<p style="text-align: right;">Page 188</p> <p>1 they were exposed at enrollment but reported being      2 unexposed as follow-up as exposed."</p> <p>3 Those are just percentages. There's no basis      4 that is reported in this paper as to why they chose      5 those percentages.</p> <p>6 Q. Okay.</p> <p>7 A. And so that is -- that is a huge assumption that      8 one would have to accept in order to accept the results      9 of this study. And without a basis to choose      10 80 percent, 90 percent, they could have chose 60, 50,      11 40, 30, 90, 95, just throwing anything out there without      12 any basis for it, then there's no way that you could      13 accept those assumptions.</p> <p>14 Q. Now, you've said in your report that it raises a      15 red flag -- and I'm trying to find it. You say it      16 raises a red flag because the results after imputation      17 were different than the results before imputation;      18 correct?</p> <p>19 A. Yeah. I'm trying to find it as well.</p> <p>20 Q. And I have it -- and I had it highlighted and I      21 wanted to give you an opportunity to explain it and I</p>
<p style="text-align: right;">Page 187</p> <p>1 you don't know what they did and what they didn't      2 because they didn't describe it; right?</p> <p>3 A. When an imputation strategy gives you different      4 results than without imputation, that's usually a      5 problem.</p> <p>6 Q. Yeah. I do want to ask you that, and I'm going      7 to get to that in a moment.</p> <p>8 In addition, you also say, "It's also unclear      9 the basis -- what the basis is for the methods used to      10 correct contradictory data"; correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Okay. Since you can't discern the methods used      13 I assume you have no opinions to a reasonable degree of      14 medical and scientific certainty as to whether or not      15 this was or was not an appropriate basis for the method?</p> <p>16 A. I actually can discern it. In the next      17 sentence, it says "In the second, third, and fourth      18 scenarios the authors classified 80 percent of the women      19 who were unexposed at enrollment but reported that they      20 were exposed during the same time period at follow-up as      21 exposed, and 90 percent of the women who claimed that</p>	<p style="text-align: right;">Page 189</p> <p>1 cannot find it on my -- oh, I see it.</p> <p>2 On the bottom of page 32, it says, "Imputation      3 strategies are often used to help provide some      4 reassurance to support and strengthen an association      5 when association actually exists. When the data without      6 imputation suggests no clear association, as in this      7 study, and data with imputation suggests otherwise, this      8 inconsistency is clearly a red flag."</p> <p>9 Do you see that?</p> <p>10 A. I do, yes.</p> <p>11 Q. You have no citation for that; right?</p> <p>12 A. No. But I have personal experience in doing      13 longitude 23459 studies where that has come up. And,      14 absolutely, I have experience in that.</p> <p>15 Q. But you do not -- you don't know -- have you      16 looked up when imputation strategies are actually used      17 and whether or not it's appropriate or not appropriate?</p> <p>18 A. I think I answered that earlier.</p> <p>19 Q. Um-hum.</p> <p>20 A. I have -- my education and training, actually,      21 as to when to use imputation strategies has governed</p>

<p style="text-align: right;">Page 190</p> <p>1 when that's been done in studies.</p> <p>2 Q. I'm actually going to come back to that. Let's</p> <p>3 go back to the study, Exhibit 3, if I could. We read on</p> <p>4 page 1 -- I'm sorry. Let's start at table 2. Scenario</p> <p>5 four.</p> <p>6 Now, this is the -- this is the -- this is the</p> <p>7 reported results that you included in your chart as</p> <p>8 being the results that the study authors claimed were</p> <p>9 results of the study; correct? You put it in your chart</p> <p>10 on, I think we said --</p> <p>11 A. The scenario four.</p> <p>12 Q. Yeah.</p> <p>13 A. The 1.82 hazard ratio with a confidence interval</p> <p>14 of 1.26 to 2.43. Yes.</p> <p>15 Q. Turn to table 3, if I could.</p> <p>16 Now, this -- what is the purpose of this table?</p> <p>17 A. So table 3 says, "The covariate adjusted hazard</p> <p>18 ratio and 95 percent confidence intervals for the</p> <p>19 association between douching and genital talc use by</p> <p>20 frequency, duration, and timing of use on the basis of</p> <p>21 models with contradictory data correction and multiple</p>	<p style="text-align: right;">Page 192</p> <p>1 because there's potentially some preconceived notion</p> <p>2 that there may be an association between disease and</p> <p>3 exposure. And, you know, certainly, if you use the</p> <p>4 example of the follow-up questionnaire that was</p> <p>5 administered 2017 to 2019, a lot of -- there were a lot</p> <p>6 of -- there was a lot of litigation right before that,</p> <p>7 and so -- and it wasn't involving breast cancer. It</p> <p>8 wasn't involving uterine cancer.</p> <p>9 So just because recall bias may exist between</p> <p>10 one potential association between exposure and outcome</p> <p>11 doesn't mean that it's going to exist for everything</p> <p>12 else.</p> <p>13 Q. Well, do you think on litigation that people</p> <p>14 truly understood the difference between ovarian cancer</p> <p>15 and uterine cancer? I mean, from a realistic point of</p> <p>16 view for women who are actually filing cases in</p> <p>17 litigation, that they appreciate -- that they're going</p> <p>18 to appreciate the distinction between talc causing</p> <p>19 ovarian cancer and talc causing uterine cancer?</p> <p>20 MR. BISHOP: Objection. Calls for speculation.</p> <p>21 THE WITNESS: I mean, they're two different</p>
<p style="text-align: right;">Page 191</p> <p>1 imputations."</p> <p>2 Q. And it looks at different outcomes, breast</p> <p>3 cancer, ovarian cancer, and uterine cancer; correct?</p> <p>4 A. That's correct.</p> <p>5 Q. Okay. And the only one that seems to be</p> <p>6 affected with an increased risk is ovarian cancer;</p> <p>7 correct?</p> <p>8 A. I mean, this is using the same point estimate as</p> <p>9 used in the scenario four.</p> <p>10 Q. Correct.</p> <p>11 A. So that would make sense.</p> <p>12 Q. And --</p> <p>13 A. But it is, because that's scenario four.</p> <p>14 Q. But it didn't happen with breast cancer. You</p> <p>15 didn't see that increased risk with breast cancer or</p> <p>16 uterine cancer; correct?</p> <p>17 A. Those are different cancers.</p> <p>18 Q. Okay. And if recall bias was an issue, wouldn't</p> <p>19 you expect to see it with both uterine cancer and breast</p> <p>20 cancer?</p> <p>21 A. Not necessarily. I mean, recall bias happens</p>	<p style="text-align: right;">Page 193</p> <p>1 organs.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Oh, I agree.</p> <p>4 But my question is: Do you think that women</p> <p>5 will always appreciate that if it's associated with</p> <p>6 ovarian cancer, it's not associated with uterine cancer?</p> <p>7 MR. BISHOP: Same objection.</p> <p>8 THE WITNESS: I don't think I can even comment</p> <p>9 on that.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Do you think there's any evidence that talc is</p> <p>12 associated with uterine cancer?</p> <p>13 A. I think the epidemiology demonstrates that</p> <p>14 there's no causal association between cosmetic talcum</p> <p>15 powder and uterine cancer.</p> <p>16 Q. How about talcum powder and breast cancer?</p> <p>17 A. I've not investigated that.</p> <p>18 Q. Okay. How about talcum powder and any other</p> <p>19 gynecologic cancer other than ovarian cancer? Putting</p> <p>20 that issue aside, have you seen any epidemiology</p> <p>21 connecting perineal use of talc and any other</p>

<p style="text-align: right;">Page 194</p> <p>1 gynecologic cancer other than ovarian cancer?</p> <p>2 A. That -- there's no epidemiologic evidence that</p> <p>3 there's a causal association between cosmetic talc and</p> <p>4 cervical cancer.</p> <p>5 Q. Okay. Any other gynecologic cancers that</p> <p>6 there's even an association, putting aside the question</p> <p>7 as to whether or not a causal inference can be made?</p> <p>8 Any other consistent association between talc</p> <p>9 and any other gynecologic cancer, putting aside ovarian</p> <p>10 cancer?</p> <p>11 A. The literature that I've at least reviewed has</p> <p>12 involved ovarian, uterine, and cervical.</p> <p>13 Q. Now, table 3 in the O'Brien 2024 study provides</p> <p>14 an adjustment for assumed recall for people who answered</p> <p>15 the supplemental questionnaire; correct? I'm sorry.</p> <p>16 Table 3. I'm looking at figure 2.</p> <p>17 A. Okay. I have figure 2. I'm sorry. What was</p> <p>18 the question?</p> <p>19 Q. The question is: Even if 25 percent of the</p> <p>20 cases who reported ever use were assumed to be nonuser,</p> <p>21 there was a still 1.41 increased risk, statistically</p>	<p style="text-align: right;">Page 196</p> <p>1 people who are saying they were users are really not</p> <p>2 users, they're still an increased risk?</p> <p>3 A. So here's the flip side of that. I hear what</p> <p>4 you're saying.</p> <p>5 Q. No. That's what they are saying. I'm not</p> <p>6 saying -- what I say is not really important.</p> <p>7 What they're saying is that; correct?</p> <p>8 A. That is what this graph saying, if we agree to</p> <p>9 certain assumptions. And if we are agreeing to</p> <p>10 scenario four, the hazard ratio of 1.8. However, even</p> <p>11 if we agree to that, 1.82, if you look at table A -- A2.</p> <p>12 So let's go to table A2 --</p> <p>13 Q. Yep.</p> <p>14 A. -- where we've got the second column there --</p> <p>15 Q. Um-hum.</p> <p>16 A. -- and we've got the percent exposed.</p> <p>17 Q. Second column. When you say second column,</p> <p>18 you're talking about --</p> <p>19 A. Second column down, ovarian cancers, 140 cases.</p> <p>20 Percent exposed, 53 percent --</p> <p>21 Q. Okay.</p>
<p style="text-align: right;">Page 195</p> <p>1 significant; correct?</p> <p>2 A. That's what that graph says. If we assume the</p> <p>3 1.82, which is scenario four.</p> <p>4 Q. Okay. Even if the authors -- even if there was</p> <p>5 assumption that 75 percent of infrequent or short-term</p> <p>6 users were assumed to be nonusers to account for recall</p> <p>7 bias, there was still an increased risk of 1.34;</p> <p>8 correct? Statistically significant.</p> <p>9 A. So if we're referring to --</p> <p>10 Q. Section B?</p> <p>11 A. -- section B on there --</p> <p>12 Q. Um-hum.</p> <p>13 A. -- where it says, "Recall bias scenario 2,</p> <p>14 proportion of ovarian cancer cases reported in</p> <p>15 infrequent short-term use reassigned to never use."</p> <p>16 So infrequent users were assigned to never users</p> <p>17 by 75 percent. That goes to 1.34. Again, assuming the</p> <p>18 scenario four hazard ratio of 1.82.</p> <p>19 Q. Right. And so what the authors here are doing</p> <p>20 is they're taking people and saying, look, even if we</p> <p>21 take a large percentage of the women and saying that</p>	<p style="text-align: right;">Page 197</p> <p>1 A. -- right?</p> <p>2 And so this is sort of -- getting at recall</p> <p>3 bias, because most of this is retrospective. So</p> <p>4 53 percent are exposed.</p> <p>5 Now, if you go to table -- sorry, column 1 or</p> <p>6 column 3, that's -- that's a 28 percent exposed,</p> <p>7 31 percent exposed. That's about a 50 percent increase</p> <p>8 in -- in the percent exposed.</p> <p>9 And if you flip that and go back to figure 2,</p> <p>10 even if we were to assume that the hazard ratio is 1.82,</p> <p>11 if we differentially misclassify people as 50 percent</p> <p>12 then that hazard ratio goes away to be nonstatistically</p> <p>13 significant.</p> <p>14 And that's exactly what this -- this is a very</p> <p>15 good way of -- of looking at recall bias because it's a</p> <p>16 sensitivity analysis that is increasingly creating more</p> <p>17 and more differential misclassification of cases. And</p> <p>18 as there's more of that, the -- the results go away,</p> <p>19 even if you were to assume that that scenario four is</p> <p>20 correct.</p> <p>21 Q. But that's not the conclusion that the authors</p>

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<p style="text-align: right;">Page 198</p> <p>1 reached at peer review; right?</p> <p>2 A. That's what these numbers mean, though.</p> <p>3 Q. But that's not what the authors concluded;</p> <p>4 right?</p> <p>5 A. But they --</p> <p>6 Q. I'm asking you -- you can disagree based upon</p> <p>7 numbers. But my -- you need to let me finish my</p> <p>8 question.</p> <p>9 You can disagree looking at the numbers, but the</p> <p>10 authors looked at the same data you did and disagreed</p> <p>11 with you; true?</p> <p>12 A. The disagreement I have is that we -- in order</p> <p>13 to accept scenario four, there are a lot of assumptions</p> <p>14 that go into scenario four to accept that as -- as the</p> <p>15 scenario to go with. And even if you did, the 1.82 in</p> <p>16 this A part of figure 2, there is a -- there's a huge</p> <p>17 discrepancy between prospective, are you using cosmetic</p> <p>18 talc, or mostly prospective, are you using cosmetic</p> <p>19 talc, to mostly retrospective.</p> <p>20 It's a doubling of the prevalence of cosmetic</p> <p>21 talc in those folks. And if you flip that around and</p>	<p style="text-align: right;">Page 200</p> <p>1 page 2. The initial personal care product questionnaire</p> <p>2 focused on two specific time frames: age 10 to 13, and</p> <p>3 12 months before enrollment.</p> <p>4 We have no disagreement about that; right?</p> <p>5 A. That's correct. I've seen the initial</p> <p>6 questionnaire.</p> <p>7 Q. The second thing is, "More detailed information</p> <p>8 about the use of douche and genital talc was obtained in</p> <p>9 the fourth follow-up questionnaire."</p> <p>10 And that's on page 3, the first sentence;</p> <p>11 correct?</p> <p>12 A. Yes. Administered 2017 to 2019.</p> <p>13 Q. Okay. And it says -- they acknowledge "data on</p> <p>14 intimate care product use was sometimes contradictory or</p> <p>15 missing"; correct?</p> <p>16 A. That's correct.</p> <p>17 Q. And they used quantitative bias analysis to</p> <p>18 implement different approaches for imputing exposure to</p> <p>19 women who initially reported never use but did not</p> <p>20 complete the follow-up questionnaire. These comparisons</p> <p>21 were crucial for understanding potential biases, as</p>
<p style="text-align: right;">Page 199</p> <p>1 using the sensitivity analysis that they're using,</p> <p>2 decreasing -- causing a 50 percent change goes from a</p> <p>3 hard ratio of 1.82 to a hazard ratio of 1.07, which is</p> <p>4 more consistent with the previous literature out there.</p> <p>5 Q. So now I'm going to actually ask you to answer</p> <p>6 my question.</p> <p>7 My question is -- I understand where you're</p> <p>8 coming from, your interpretation of the data. You would</p> <p>9 agree with me that the authors, the NIH authors,</p> <p>10 disagreed with your -- disagreed with the conclusions</p> <p>11 that are drawn from the data; true?</p> <p>12 A. I -- not necessarily. That's not exactly what</p> <p>13 I'm saying. They are not reporting everything --</p> <p>14 Q. Okay.</p> <p>15 A. -- in this -- because, again, this is a thought</p> <p>16 experiment because of --</p> <p>17 Q. Okay.</p> <p>18 A. -- all of the assumptions that go into agreeing</p> <p>19 to a scenario to actually perform the rest of the</p> <p>20 analysis.</p> <p>21 Q. Let's go back to the study. Exposures, on</p>	<p style="text-align: right;">Page 201</p> <p>1 women with incident cancers were overrepresented in the</p> <p>2 undefined group"; correct?</p> <p>3 A. So we just looked at the quantitative bias</p> <p>4 analyses and figures --</p> <p>5 Q. I'm just asking you what they said.</p> <p>6 A. That's what they say. Yes.</p> <p>7 Q. Okay. And sometimes the reason why they</p> <p>8 couldn't do a follow-up questionnaire is because the</p> <p>9 patient died; right?</p> <p>10 A. Or just didn't answer it.</p> <p>11 Q. Or didn't answer; right?</p> <p>12 And so trying to figure out impute data is</p> <p>13 something that is typically done. That's what you've</p> <p>14 talked about before; correct?</p> <p>15 A. It is a strategy to try to get at missing data.</p> <p>16 Q. It's not unscientific is my question.</p> <p>17 A. It is not unscientific. It's actually very</p> <p>18 scientific.</p> <p>19 Q. Okay.</p> <p>20 A. But the methods and assumptions that go into the</p> <p>21 imputation of data are critical.</p>

<p style="text-align: right;">Page 202</p> <p>1 Q. Okay. Now, under statistical analysis, it says,      2 "Estimating hazard ratios for ever verse never use we      3 considered the effects of frequent use, long-term use,      4 and used during specific time range -- specific age      5 periods."</p> <p>6 You have no problem with them doing that, do      7 you?</p> <p>8 A. That seems pretty reasonable.</p> <p>9 Q. Okay. The quantitative bias analysis,      10 category four, contradictory data correction with      11 multiple imputation or missing, undefined data.</p> <p>12 Do you see that? That's what they did.</p> <p>13 A. Well, they did four different -- four different      14 scenarios.</p> <p>15 Q. Right.</p> <p>16 But the fourth one was contradictory data      17 correction with multiple imputation or -- of missing or      18 undefined data?</p> <p>19 A. That's correct.</p> <p>20 Q. Okay. In the discussion section, it says,      21 "Using newly collected data on intimate care products</p>	<p style="text-align: right;">Page 204</p> <p>1 and my opinion is that is a red flag when scenario four      2 dramatically is different than scenario one and two.</p> <p>3 Q. They go on to say on the second paragraph -- so      4 I assume you disagree with that sentence there?</p> <p>5 A. So we're probably being semantic with words.</p> <p>6 They found evidence based on the scenario that they      7 chose. That -- I'm not disagreeing with the number that      8 they're presenting.</p> <p>9 Q. You disagree that they chose that number?</p> <p>10 A. I'm disagreeing with -- I'm concerned with the      11 assumptions that go into a choosing of that number.</p> <p>12 Q. The next one I want to ask you about is it      13 says -- it says -- next column, third paragraph down,      14 "Our findings of a positive association between genital      15 talc use and ovarian cancer are consistent with previous      16 studies. Pooled analyses or meta-analyses of case      17 control studies have reduced odds ratios of 1.2 to 1.4."</p> <p>18 I assume you -- do you agree with or disagree      19 with that?</p> <p>20 A. So, I mean, if we're looking at pooled analyses,      21 you know, that number in general has landed in the 1.3</p>
<p style="text-align: right;">Page 203</p> <p>1 used in a large cohort of U.S. women, we found evidence      2 supporting a positive association between ever genital      3 talc use and incident ovarian cancer."</p> <p>4 I assume you disagree with that?</p> <p>5 A. I had a difficult time getting to the      6 discussion. Can you just point me where that is so I      7 could look at it?</p> <p>8 Q. It's page 13.</p> <p>9 A. I know. But what --</p> <p>10 Q. Under the first sentence under "discussion."      11 "Using newly collected data on intimate care      12 product use in a large cohort of U.S. women, we found      13 evidence supporting a positive association between      14 genital talc use and incident ovarian cancer."</p> <p>15 And I assume you disagree with that?</p> <p>16 A. So the results of their scenario four suggest      17 that because there's a hazard ratio of 1.82 with a      18 confidence interval that does not go -- does not      19 cross 1.</p> <p>20 However, in order to accept scenario four, there      21 are a lot of assumptions that go into that, and it's --</p>	<p style="text-align: right;">Page 205</p> <p>1 range. But, you know, those are mainly related to the      2 case control studies.</p> <p>3 Q. Well, she's -- they're saying here, "Our      4 findings in this cohort study are consistent with that."</p> <p>5 And do you agree with that or disagree with      6 that?</p> <p>7 A. Again, I'm -- there are four different scenarios      8 that they -- that they're proposing, and what they're      9 referring to is scenario four --</p> <p>10 Q. Okay.</p> <p>11 A. -- which I have concern with.</p> <p>12 Q. Okay.</p> <p>13 A. And -- because of all of the things that we      14 talked about before.</p> <p>15 Q. Now, it then goes on to say -- and this goes      16 back to O'Brien 2020 -- that "the hazard ratio from a      17 pooled analysis of prospective cohort studies also      18 indicated a positive, albeit small, association. And as      19 previously noted, this effect estimate is likely biased      20 towards the null because of nondifferential and      21 misclassification exposure."</p>

<p style="text-align: right;">Page 206</p> <p>1 See that?</p> <p>2 A. I do.</p> <p>3 Q. And they're referring to O'Brien 2020; right?</p> <p>4 A. They are. But, you know, these authors are just</p> <p>5 saying a positive small association and just stating the</p> <p>6 hazard ratio and not the confidence interval which</p> <p>7 flanks one, which is --</p> <p>8 Q. And they're also saying it probably</p> <p>9 underestimates it because of nondifferential</p> <p>10 classification; correct?</p> <p>11 A. Well, I see what they're saying, but I don't</p> <p>12 know how they come about that.</p> <p>13 Q. All right. But they've been pretty consistent.</p> <p>14 We looked at the letter to the editor. We've looked at</p> <p>15 the various other articles they've wrote characterizing</p> <p>16 their results in O'Brien 2020.</p> <p>17 And this is fully consistent with what they've</p> <p>18 been saying all along; right?</p> <p>19 A. Well, nondifferential misclassification usually</p> <p>20 does bias towards the null, but there's -- there's no</p> <p>21 provided evidence to suggest that nondifferential</p>	<p style="text-align: right;">Page 208</p> <p>1 paragraph on 34 on my report and the first sentence of</p> <p>2 page 13, second paragraph, second column.</p> <p>3 Q. But they explained what they meant by that in</p> <p>4 the next couple sentences in the report; right? In the</p> <p>5 article; correct?</p> <p>6 They say, "Those reporting talc use could be</p> <p>7 recalling products that contained talc, cornstarch, or a</p> <p>8 mixture, and women may have used different products at</p> <p>9 different times. Some talc may have been contaminated</p> <p>10 with asbestos or other potentially harmful chemicals,</p> <p>11 such as phthalates or parabens. Chronic irritation of</p> <p>12 the ovaries or fallopian tubes from talc or talc-like</p> <p>13 products could potentially contribute to" -- I can never</p> <p>14 say that word -- "carcinogenesis"; right?</p> <p>15 A. I mean, those are all hypotheses.</p> <p>16 Q. Right.</p> <p>17 And what they're saying is even though they find</p> <p>18 that talc -- they're finding that cosmetic powders are</p> <p>19 associated with ovarian cancer, they can't pinpoint</p> <p>20 exactly which of the constituents of the powder is the</p> <p>21 culprit; true?</p>
<p style="text-align: right;">Page 207</p> <p>1 misclassification is actually happening.</p> <p>2 Q. Okay. Now, you say -- in your report, you refer</p> <p>3 to the prior paragraph here.</p> <p>4 It says, "These results do not establish</p> <p>5 causality," and you kind of stop there.</p> <p>6 When -- you see that quote that you have here?</p> <p>7 MR. BISHOP: What page are you referring to?</p> <p>8 MR. TISI: Page 13 of the report.</p> <p>9 BY MR. TISI:</p> <p>10 Q. And it says -- it says, "I agree with the</p> <p>11 authors. However, the extent to which they say these</p> <p>12 results do not establish causality and do not implicate</p> <p>13 any specific cancer-inducing agent?"</p> <p>14 Do you see? That's the last sentence of your</p> <p>15 section on O'Brien; right?</p> <p>16 A. Yes. That's correct.</p> <p>17 Q. And that's the first sentence of that paragraph;</p> <p>18 true? The first sentence of the paragraph in O'Brien</p> <p>19 2024 on the top of page 13 on the right-hand side.</p> <p>20 A. I'm sorry. I was looking at my report.</p> <p>21 Yeah. It's the last sentence of the first</p>	<p style="text-align: right;">Page 209</p> <p>1 A. No. What they're saying is these -- the results</p> <p>2 of this study do not establish causality and do not</p> <p>3 implicate any specific cancer-inducing agent, regardless</p> <p>4 of what's in the cosmetic talc.</p> <p>5 Q. Well, they actually say in later -- in the last</p> <p>6 paragraph of the study, they reiterate that point over</p> <p>7 again.</p> <p>8 They say, "Overall, our findings support" --</p> <p>9 last paragraph -- "the hypothesis that there is a</p> <p>10 positive association between genital talc use and</p> <p>11 ovarian cancer incidence, although they do not pinpoint</p> <p>12 a specific cause or mechanism."</p> <p>13 Do you see that?</p> <p>14 A. I do, yes.</p> <p>15 Q. Okay. And so what -- I mean, I'm trying to</p> <p>16 paraphrase here because I'm trying to understand what</p> <p>17 they're saying.</p> <p>18 They're saying is, look, there is an overall</p> <p>19 association in our view. We just can't tell you which</p> <p>20 of the constituents might be the culprit; true? If you</p> <p>21 look at those two together.</p>

<p style="text-align: right;">Page 210</p> <p>1 A. I mean, they're saying different things. The      2 paragraph -- second paragraph on page 13 says, "These      3 results do not establish causality and do not implicate      4 any specific cancer-inducing agent."</p> <p>5 That -- I don't know how it could be any      6 clearer. They're saying that there's no causality.</p> <p>7 Q. Okay.</p> <p>8 A. In this study.</p> <p>9 Q. Well, let's see --</p> <p>10 A. And now they're saying the last thing, "Overall,      11 our findings support a hypothesis" -- the hypothesis      12 that there's an positive association between genital      13 talc use and ovarian cancer incidence, although they do      14 not pinpoint a specific cause or mechanism. And that's      15 only if you assume that they're scenario four is --</p> <p>16 Q. Okay.</p> <p>17 A. -- with all of its assumptions, which none of      18 them are based on anything.</p> <p>19 Q. All right. So let's talk about your -- on      20 page 32 of your report, you say, "Table A2 represents      21 the prospective data without imputation of missing</p>	<p style="text-align: right;">Page 212</p> <p>1 prior testimony.</p> <p>2 THE WITNESS: That's not an assumption. That      3 is -- that is -- that is practice.</p> <p>4 BY MR. TISI:</p> <p>5 Q. You know that people disagree with you on that;      6 correct? Including O'Brien.</p> <p>7 A. I think we've talked about this in the past.</p> <p>8 Q. Right.</p> <p>9 But you know that people disagree with --</p> <p>10 that's -- the statement you just made assumes that there      11 is a cut point on statistical significance; right?</p> <p>12 A. In order to -- for studies not to be chaotic,      13 there is a reason for statistical significance.</p> <p>14 Q. Now, would you agree with the statement that the      15 reliability of fully prospective cohort data is fully      16 dependent on whether the women in this study were      17 properly characterized as users or nonusers in the first      18 instance?</p> <p>19 A. Can you read that -- can you say that again?</p> <p>20 Q. Yeah.</p> <p>21 Do you agree -- do you agree that the</p>
<p style="text-align: right;">Page 211</p> <p>1 data"; correct?</p> <p>2 A. That is correct.</p> <p>3 Q. Okay. And you say that, "This data, which is      4 fully prospective, is the most reliable"; correct?</p> <p>5 A. I didn't say that it was the most reliable. I      6 said it's highly relevant and central to the      7 interpretation of the results of this study.</p> <p>8 Q. The fully prospective data is in the first      9 column on page -- of this table A2; right?</p> <p>10 A. There are two columns of fully prospective data.      11 One is the first column, and then the third column is      12 also fully prospective data of incident ovarian cancer      13 cases.</p> <p>14 Q. And --</p> <p>15 A. Both of which show that there is not a      16 statistically significant association between cosmetic      17 talc use and ovarian cancer.</p> <p>18 Q. That's assuming that statistical significance is      19 the cut point for an association and not? We won't go      20 back over that. But that is your assumption; correct?</p> <p>21 MR. BISHOP: Objection. Mischaracterizes his</p>	<p style="text-align: right;">Page 213</p> <p>1 reliability of the fully prospective cohort data is      2 dependent upon whether the women were properly      3 characterized as users or nonusers at enrollment?</p> <p>4 A. I would say that in a cohort study, when you are      5 collecting information prospectively, it is important to      6 properly characterize someone as exposed or unexposed,      7 whatever outcome you're looking at.</p> <p>8 Q. Okay. And so in this case, in the Sister Study,      9 the initial questionnaire that we have been talking      10 about left out, potentially, decades of potential use;      11 true?</p> <p>12 MR. BISHOP: Objection. Asked and answered.</p> <p>13 THE WITNESS: In the original Gonzalez --</p> <p>14 BY MR. TISI:</p> <p>15 Q. Yes.</p> <p>16 A. -- study, yes. There was the possibility of      17 that.</p> <p>18 Q. All right. And so do you fault the O'Brien      19 authors for trying to collect additional data for the      20 potentially decades of missing data between the ages      21 13 and 12 months before whatever day they enrolled?</p>

<p style="text-align: right;">Page 214</p> <p>1 A. You know, I'm not aware of whether or not    2 Dr. O'Brien is involved in the -- the putting forth the    3 questionnaires. But -- I'm just --    4 Q. Not to quibble with you here. Let me --    5 A. I'm just getting at, like, the --    6 Q. Let me withdraw it and rephrase the question.    7 Do you quibble at all with the authors    8 recognizing that there's a big hole in the initial    9 questionnaire of trying to collect additional data about    10 what happened between age 13 and 12 months before the    11 time in which they the enrolled in the Sister Study?    12 A. I hear what you're saying. No, I do not.    13 And --    14 Q. Okay.    15 A. -- the addition -- I just don't have any    16 information on who created or who decided to have the    17 follow-up questionnaire.    18 Q. Okay. So if you go to the study on page 13,    19 that's why they did it; right? That's why they did the    20 initial questionnaire -- the additional questionnaire;    21 right?</p>	<p style="text-align: right;">Page 216</p> <p>1 using talc in her 20s and 30s and up until 49 years old;    2 right?    3 A. And her to answer that she never used it?    4 Q. That she never used it.    5 A. It's possible.    6 Q. And getting -- and she would be characterized --    7 if, in fact, that hypothetical happened and she used    8 talc for 25 years but that wasn't captured in the    9 original questionnaire, she would be characterized as a    10 nonuser, and that would be untrue; right?    11 A. That is a possibility. Yes.    12 Q. And that's why the authors asked the additional    13 questions on the supplemental questionnaire; right?    14 A. Well, again, I don't know if the authors decided    15 to create a supplemental questionnaire or the    16 supplemental questionnaire was created and then the    17 authors said, "Hey, we've got this supplemental    18 questionnaire. Let's try to use it now."    19 Q. Okay. Now, if -- on contradictory data    20 correction, if you get new information in a cohort study    21 that shows that somebody was improperly characterized as</p>
<p style="text-align: right;">Page 215</p> <p>1 A. Where are you referring?    2 Q. I'm looking for it. Page 13 of the article.    3 Okay. I can't find it in here. I know it's in here,    4 but I'll just move on.    5 MR. BISHOP: Is this a good time to take a lunch    6 break? Or do you want to --    7 (Off the record.)    8 BY MR. TISI:    9 Q. Let's kind of use a concrete example; right?    10 Because I want the record to kind of like make sense to    11 somebody who reads this, because this is heavy stuff    12 here. Okay?    13 So if I enroll -- if a woman gets enrolled at    14 50 years old in an original -- let's call her    15 Mrs. Smith. She gets enrolled in the study at age    16 50 years old; right?    17 The initial questionnaire asks her, "Were you    18 ever exposed to talc at ages 10 to 13 or 12 months    19 before the study?"    20 If she can answer that question truthfully,    21 she'd say no. But there's also the possibility of her</p>	<p style="text-align: right;">Page 217</p> <p>1 being exposed -- not exposed but you subsequently learn    2 that they are exposed, wouldn't it be scientifically    3 inappropriate not to address that question?    4 A. So that's part of the contradictory data    5 correction that was used.    6 Q. And you have no problem with that?    7 A. No. Because the issue is if in the first    8 questionnaire somebody took it when they were 30 and    9 they said, "No. I didn't use it when I was 12 or 13 or    10 when I was 13 to 15," whatever, 13 years old and, "No.    11 I'm not using it within the 12 months prior,"    12 30-year-old, but then they're asked in the follow-up;    13 right? And they say, "Yes. I used it when I was in my    14 20s, my 30s, my" -- that's contradictory data.    15 Q. Right.    16 A. And if it is age appropriate, then --    17 Q. Well, it's not contradictory data because it    18 doesn't contradict what they said. It contradicts the    19 category in which they were placed; right?    20 A. That's semantic. I mean, that's saying the same    21 thing.</p>

<p style="text-align: right;">Page 218</p> <p>1 Q. No, it isn't. No. Let's be fair here. Okay?</p> <p>2 If they said that they -- if they were asked</p> <p>3 specific questions about their talc use and they were</p> <p>4 not -- and the study authors, the study investigators</p> <p>5 characterized them as nonusers, they would not -- were</p> <p>6 not nonusers if they used in their 20s, 30s, and 40s.</p> <p>7 The investigator simply didn't ask the right question;</p> <p>8 right?</p> <p>9 A. So I think we're talking about two different</p> <p>10 things. I'm talking about once the supplementary</p> <p>11 questionnaire is used --</p> <p>12 Q. Okay.</p> <p>13 A. -- and then there's differences in what someone</p> <p>14 reports in the first one and the second one. That's --</p> <p>15 Q. But it's not different. That's what I'm trying</p> <p>16 to get at here.</p> <p>17 If somebody says -- if I say I was exposed at</p> <p>18 age -- I was not exposed at age -- I'm 63. I was not</p> <p>19 exposed -- between age 10 and age 13, and I wasn't</p> <p>20 exposed at 62 to 63; right? I answered those questions</p> <p>21 honestly; right?</p>	<p style="text-align: right;">Page 220</p> <p>1 Q. But they did that just to see --</p> <p>2 A. As a thought experiment.</p> <p>3 Q. -- what the outer bounds are; right?</p> <p>4 A. That's right. And that's the thought experiment</p> <p>5 here.</p> <p>6 Q. Right.</p> <p>7 A. And then they designed scenario four with a lot</p> <p>8 of assumptions in it to create that, whereas the bounds</p> <p>9 are likely -- you've got scenario three where everyone</p> <p>10 is labeled. You've got scenario one where there's some</p> <p>11 missing data and imputations. And then you got scenario</p> <p>12 two which is kind of in between.</p> <p>13 Q. And --</p> <p>14 A. And then you have A2 with column 1, and you've</p> <p>15 got A2 with column 3 fully prospective in line with the</p> <p>16 cohort studies from previous.</p> <p>17 Q. So -- and that's why they did number four.</p> <p>18 That's why they did scenario number four was to try to</p> <p>19 correct for the extremes in scenario number 3; right?</p> <p>20 A. Scenario 3 is complete differential</p> <p>21 misclassification of exposure, which is why the hazard</p>
<p style="text-align: right;">Page 219</p> <p>1 If they asked a supplemental questionnaire that</p> <p>2 asks me did you use the product in my 40s and 50s and I</p> <p>3 answer yes, that's not contradicting my original answers</p> <p>4 in the questionnaire. That just provides supplemental</p> <p>5 information that wasn't asked in the first place; right?</p> <p>6 A. But when you look at that, someone would be --</p> <p>7 if you just went on the first questionnaire labeled</p> <p>8 unexposed and if you just went on the follow-up</p> <p>9 questionnaire labeled as exposed -- so the authors had</p> <p>10 an analysis planned to deal with that potential</p> <p>11 contradiction in the reporting because it's different</p> <p>12 data, because someone is labeled unexposed at first and</p> <p>13 then exposed.</p> <p>14 Q. Do you have any problem with them looking and</p> <p>15 saying, you know, on retrospect, we now know they were</p> <p>16 exposed, we're going to take them out of the unexposed</p> <p>17 group and make them exposed?</p> <p>18 A. Only with the extreme. And that's scenario</p> <p>19 three where the unexposed, all of the missing data was</p> <p>20 labeled as exposed. And that -- that's actually the</p> <p>21 extreme of an imputation, where you --</p>	<p style="text-align: right;">Page 221</p> <p>1 ratio is so high.</p> <p>2 Q. And that's why they did the correction in</p> <p>3 number four; right?</p> <p>4 A. They did corrections in one, two, and four, and</p> <p>5 my concerns with four, there are a lot of assumptions</p> <p>6 that go into that to create scenario four.</p> <p>7 Q. How many women in O'Brien who are missing in</p> <p>8 enrollment were missing on follow-up?</p> <p>9 A. I don't have the study memorized. I'd have to</p> <p>10 look at it.</p> <p>11 Q. How many women were identify as nonusers on the</p> <p>12 initial restrictive questionnaire that did not provide</p> <p>13 follow-up information or could not because they died?</p> <p>14 A. Again, I don't have -- I mean, this is a very,</p> <p>15 very complicated paper. I don't have the numbers.</p> <p>16 Q. If I told you 37, does that make sense?</p> <p>17 A. I know that there's a table. I just don't have</p> <p>18 them memorized. And it looks like we're talking about</p> <p>19 table -- not this one. It's the supplemental table.</p> <p>20 Q. All right.</p> <p>21 A. And it would be helpful to look at. Yeah. It</p>

<p style="text-align: right;">Page 222</p> <p>1 looks like it's supplemental table A5.</p> <p>2 Q. And this is called missingness in epidemiology;</p> <p>3 right?</p> <p>4 A. I guess. I mean, we just call it missing data.</p> <p>5 Q. And the method to deal with missingness and the</p> <p>6 way to deal with this is known as is multiple</p> <p>7 imputation; correct?</p> <p>8 A. That is one of the strategies to deal with</p> <p>9 missing data.</p> <p>10 Q. And multiple imputation is fully described in</p> <p>11 the literature; correct?</p> <p>12 A. I mean, it's described in the literature. It's</p> <p>13 taught in classes and it's --</p> <p>14 Q. In fact, it's --</p> <p>15 A. -- performed with statistical packages.</p> <p>16 Q. Right.</p> <p>17 And is single imputation or multiple imputation</p> <p>18 more reliable?</p> <p>19 MR. BISHOP: Objection to form. Vague.</p> <p>20 Overbroad.</p> <p>21 THE WITNESS: So it really depends. It depends</p>	<p style="text-align: right;">Page 224</p> <p>1 missing data is to compare the groups. And if</p> <p>2 someone -- if you have a group of nonmissing data and</p> <p>3 you have a group of -- with missing data, if those</p> <p>4 groups are very different, then you're -- you're likely</p> <p>5 to get differences in your point estimate regardless of</p> <p>6 what kind of imputation strategy you use is.</p> <p>7 Q. My question is different.</p> <p>8 Before the statistician applies multiple</p> <p>9 imputation, do they know -- can they predict ahead of</p> <p>10 time whether or not it will attenuate and exaggerate a</p> <p>11 risk?</p> <p>12 A. And I'm going to answer the same way, because</p> <p>13 that's not a multiple imputation. That is a -- the</p> <p>14 beginning of performing an imputation analysis. And if</p> <p>15 they're dramatically different, then there's an issue.</p> <p>16 And that wasn't done in this paper.</p> <p>17 Q. I didn't mean to interrupt. I'm sorry.</p> <p>18 A. I'm done. Thanks.</p> <p>19 Q. Okay. At the bottom of page 2 of your first</p> <p>20 concern, you say, "Imputation strategies are often used</p> <p>21 to help provide some reassurance to support and</p>
<p style="text-align: right;">Page 223</p> <p>1 on the variables that you're trying to impute. If we</p> <p>2 use the example of lung function, you may just have to</p> <p>3 just impute that one variable, and your one time doing</p> <p>4 that would be a single imputation.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Okay.</p> <p>7 A. Multiple imputations would involve doing it a --</p> <p>8 like, a whole repetition of times, 100 times, and if all</p> <p>9 100 come out of, that kind of thing, or ten times.</p> <p>10 Q. In a study like this, do you quibble with the</p> <p>11 use of multiple imputation to deal with the question of</p> <p>12 missingness?</p> <p>13 A. In a study like this, multiple imputation would</p> <p>14 be a way to try to get at missingness.</p> <p>15 Q. And just to be clear, when a statistician</p> <p>16 applies multiple imputation to a missing data, a</p> <p>17 statistician doesn't know ahead of time how that will</p> <p>18 affect the hazard ratio, does it -- do they? It can</p> <p>19 either attenuate the risk or exaggerate the risk?</p> <p>20 A. So I'm going to say it depends because the first</p> <p>21 step in performing an analysis where you're looking at</p>	<p style="text-align: right;">Page 225</p> <p>1 strengthen association when the association actually</p> <p>2 exists," and then you talk about the red flag.</p> <p>3 Are you talking about single imputation or</p> <p>4 multiple imputation or both?</p> <p>5 A. I -- in general, I'm talking about an imputation</p> <p>6 strategy. When it changes things dramatically, it has</p> <p>7 to cause pause for reflection.</p> <p>8 Q. Do you know -- do you have any paper or article</p> <p>9 to support your position that it is only used to</p> <p>10 strengthen an association when an association actually</p> <p>11 exists, or is that just your experience?</p> <p>12 A. That's my experience and training. Yes.</p> <p>13 Q. Do you know whether or not that's supported in</p> <p>14 the literature?</p> <p>15 A. I don't. But I've got 20 years of practice.</p> <p>16 Q. On page 4 of the article, it talks about why</p> <p>17 they did multiple imputation and it talks about</p> <p>18 footnote 4. Footnote 4 is a study -- excuse me -- is a</p> <p>19 study -- author by the name or Royston.</p> <p>20 You see that?</p> <p>21 A. I don't. You're on page what? I'm sorry.</p>

<p style="text-align: right;">Page 226</p> <p>1 Q. I'm sorry. I'm finding it here. Hold on a 2 second. Article on page 4.</p> <p>3 MR. BISHOP: While he's looking, the important 4 thing is whether the court reporter and you need a break 5 for lunch or whether you want to proceed without lunch. 6 It's really not important whether Counsel --</p> <p>7 MR. TISI: Yeah, no. I agree with you. I 8 thought we were...</p> <p>9 MR. BISHOP: That's fine. I asked him. And 10 the --</p> <p>11 THE WITNESS: Are you okay? 12 (Recess taken.)</p> <p>13 BY MR. TISI:</p> <p>14 Q. So I found what I was looking for. On the study 15 itself, it talks about -- on page 4, at the top right, 16 it says, "We did this for each, ten copies of data 17 summarizing hazard ratios using -- at 95 percent 18 confidence intervals using Rubin's rules."</p> <p>19 Do you see that?</p> <p>20 MR. BISHOP: I showed him where it is.</p> <p>21 THE WITNESS: I do, yes.</p>	<p style="text-align: right;">Page 228</p> <p>1 A. Yes. But you're referring to 32; right? 2 Q. Yes.</p> <p>3 A. Instead of 31?</p> <p>4 Q. I think it's 32. It's -- 32. Right. Right. 5 And they -- let's just talk about this article. Just 6 cite it. This is Imputing Multiple [sic] Covariant 7 Values for the Cox Model by Wright and Royston. 8 And if you look at the summary, is there any 9 limitation to using multiple imputation where there is 10 only to support evidence of an association?</p> <p>11 A. Well, number one, I've never read this article. 12 I'm not familiar with it. I am familiar with multiple 13 imputation in using the Cox model, but I would have to 14 read this article to comment on it.</p> <p>15 Q. And you had not looked at the article that they 16 actually cited in support of what they did to see 17 whether or not your assertion -- un-cited assertion that 18 it's only used to strengthen association was valid?</p> <p>19 A. Can you ask that again?</p> <p>20 Q. Yes.</p> <p>21 You did not look at the article that they cited</p>
<p style="text-align: right;">Page 227</p> <p>1 BY MR. TISI:</p> <p>2 Q. And that involves multiple imputation; correct?</p> <p>3 A. Yes. That would be considered multiple 4 imputation.</p> <p>5 Q. If you look at the back of the study, they cite 6 an article by White and Royston in support of that.</p> <p>7 Do you see that? It's footnote 31.</p> <p>8 A. Yeah. Looks like it's a chapter of a book.</p> <p>9 Q. I'm going to show you that and make that 10 Exhibit Number --</p> <p>11 MS. PARFITT: That is Exhibit Number 20.</p> <p>12 MR. TISI: 20.</p> <p>13 (Deposition Exhibit 20 was marked.)</p> <p>14 BY MR. TISI:</p> <p>15 Q. Have you seen that article before? And I 16 actually highlighted the parts that I'm going to ask you 17 about.</p> <p>18 Do you see the article? It's called "Imputing 19 Missing Covariate Values for the Cox Model," and they 20 used this as the -- as the authority to support what 21 they were doing?</p>	<p style="text-align: right;">Page 229</p> <p>1 to see whether they appropriately used multiple 2 imputation to correct this particular data?</p> <p>3 A. I did not specifically look at this article. 4 I did look at this paragraph which describes how they 5 performed the multiple imputation for the fourth 6 scenario.</p> <p>7 Q. The next article that I want to ask you about is 8 number --</p> <p>9 MS. PARFITT: 21.</p> <p>10 MR. TISI: 21.</p> <p>11 (Deposition Exhibit 21 was marked.)</p> <p>12 BY MR. TISI:</p> <p>13 Q. And this is an article in JAMA by, among others, 14 Elizabeth Stuart, who is the chair of the department of 15 biostatistics.</p> <p>16 Have you --</p> <p>17 MR. BISHOP: Do you have one more copy?</p> <p>18 MR. TISI: What?</p> <p>19 MR. BISHOP: I gave him --</p> <p>20 MR. TISI: Oh, I'm sorry.</p> <p>21 MR. BISHOP: All right.</p>

<p style="text-align: right;">Page 230</p> <p>1 BY MR. TISI:</p> <p>2 Q. Have you seen this article?</p> <p>3 MR. BISHOP: Thanks.</p> <p>4 THE WITNESS: Not to my recollection. No.</p> <p>5 BY MR. TISI:</p> <p>6 Q. I'm going to ask you -- I'm going to tell you</p> <p>7 that I have tried to search as many different articles</p> <p>8 as I could think of on multiple imputation, and I have</p> <p>9 never seen the limitation that you placed on it that you</p> <p>10 would only use it when -- to strengthen an association.</p> <p>11 Are you telling me that there is such an</p> <p>12 article?</p> <p>13 MR. BISHOP: I'm sorry. I'm just going to</p> <p>14 object to the comments of counsel.</p> <p>15 THE WITNESS: So --</p> <p>16 BY MR. TISI:</p> <p>17 Q. Other than your experience -- I understand</p> <p>18 you're experienced.</p> <p>19 A. Yeah.</p> <p>20 Q. I just want to know a textbook, an article,</p> <p>21 literature, any place where anybody with expertise in</p>	<p style="text-align: right;">Page 232</p> <p>1 experience because --</p> <p>2 BY MR. TISI:</p> <p>3 Q. Okay.</p> <p>4 A. -- because we use multiple imputation to handle</p> <p>5 missing data. And when you get two clearly different</p> <p>6 results based on whether you impute or not, that is a</p> <p>7 red flag.</p> <p>8 Q. Let's talk about one of the things that -- and</p> <p>9 that's your opinion. You hold that to a reasonable</p> <p>10 degree of scientific certainty, even without a citation?</p> <p>11 A. Absolutely.</p> <p>12 Q. Okay. Now, unmeasured confounding, you -- the</p> <p>13 authors say that they can't rule out unmeasured</p> <p>14 confounding; correct?</p> <p>15 A. That's what they say.</p> <p>16 Q. All right. They don't think it's recall bias</p> <p>17 but they say, "Risk could theoretically be the result of</p> <p>18 unmeasured confounding"; true?</p> <p>19 A. Can you point to where we're looking at on the</p> <p>20 paper?</p> <p>21 Q. I mean, I can go back. It's the very last --</p>
<p style="text-align: right;">Page 231</p> <p>1 biostatistics has indicated that you only use it to</p> <p>2 strengthen association and if you use it any other</p> <p>3 place, it raises a red flag?</p> <p>4 A. So let me just read what I said.</p> <p>5 Imputation strategies are often used to provide</p> <p>6 some reassurance to support and strengthen association</p> <p>7 when that association actually exists.</p> <p>8 That is -- I'm saying that it provides some</p> <p>9 reassurance, meaning that if you have a lot of missing</p> <p>10 data --</p> <p>11 Q. Well, you didn't finish what you wrote. So</p> <p>12 let's keep -- "when the data without imputation shows no</p> <p>13 clear association, as in this study, and data with</p> <p>14 imputation suggests otherwise, this inconsistency is a</p> <p>15 clearly a red flag."</p> <p>16 I haven't seen anything in the literature that</p> <p>17 I've been able to find that would support that</p> <p>18 statement. You don't make a citation to it. And other</p> <p>19 than your experience, could you tell me where that is?</p> <p>20 MR. BISHOP: Same objection.</p> <p>21 THE WITNESS: I'm going to stand by my</p>	<p style="text-align: right;">Page 233</p> <p>1 actually, where I got that from is in the box. On</p> <p>2 page 2, the relevance in the box right here.</p> <p>3 It says, "These findings support the hypothesis</p> <p>4 that there is a positive association between genital</p> <p>5 talc use and development of ovarian cancer, but</p> <p>6 unmeasured confounding could still be present."</p> <p>7 Do you see that?</p> <p>8 A. I do. That's written by the associate editor.</p> <p>9 Q. Do you agree with that statement? Do you think</p> <p>10 confounding is a more -- let me --</p> <p>11 Apart from the theoretical possibility, do you</p> <p>12 think confounding is a realistic -- unmeasured</p> <p>13 confounding is a realistic explanation for this data?</p> <p>14 A. Unmeasured confounding is always a concern --</p> <p>15 Q. Right.</p> <p>16 A. -- in studies.</p> <p>17 Q. How likely is it a concern here is what I'm</p> <p>18 trying to say.</p> <p>19 In your view, is it more likely than not that</p> <p>20 this would -- that these results related to confounding?</p> <p>21 A. Which results are you talking about?</p>

<p style="text-align: right;">Page 234</p> <p>1 Q. The results of the study.</p> <p>2 A. Yeah, but which scenario?</p> <p>3 Q. I'm testing -- I'm testing that these findings</p> <p>4 support the hypothesis that there's a positive</p> <p>5 association between genital talc use and the development</p> <p>6 of ovarian cancer, but unmeasured confounding could</p> <p>7 still be present."</p> <p>8 And I'm asking you: A, do you believe that</p> <p>9 unmeasured confounding could explain scenario four? And</p> <p>10 if you do, how big would that confounder have to be in</p> <p>11 order to explain a relative risk -- a hazard ratio of</p> <p>12 1.81?</p> <p>13 A. Could residual confounding affect any of these</p> <p>14 scenarios? Sure.</p> <p>15 Q. Okay.</p> <p>16 A. Because you're not asking these research</p> <p>17 subjects every question known to humankind.</p> <p>18 Q. Right.</p> <p>19 And I'm asking you how likely -- I mean, other</p> <p>20 than that it's a theoretic possibility, how likely would</p> <p>21 it be that there would be an unmeasured confounder that</p>	<p style="text-align: right;">Page 236</p> <p>1 litigation, because they would say it was a</p> <p>2 ridiculous study. So let's -- we can move on from</p> <p>3 there.</p> <p>4 But let's go back to this. How big would the</p> <p>5 confounder in terms of magnitude have to be to explain</p> <p>6 an 80 percent increased risk that is predicted in this</p> <p>7 study on scenario four?</p> <p>8 A. It would just have to be linked to the exposure</p> <p>9 and linked to the outcome and not related to the causal</p> <p>10 pathway.</p> <p>11 Q. And so the magnitude -- you would not have to</p> <p>12 have an assessment of the magnitude of that risk</p> <p>13 provided by that confounder to explain a 1.8? What I'm</p> <p>14 trying to get at here -- had to be a pretty significant</p> <p>15 confounder to explain a 1.8 relative risk, wouldn't it?</p> <p>16 A. It depends what you mean by "significant."</p> <p>17 If you go back and look at the studies looking</p> <p>18 at the risk of pancreatic cancer and coffee drinking,</p> <p>19 and what it just turned out to be is that more coffee</p> <p>20 drinkers were smokers and that was the reason for the</p> <p>21 pancreatic cancer development and it had nothing to do</p>
<p style="text-align: right;">Page 235</p> <p>1 would explain these results?</p> <p>2 A. So there's no way that anyone could say a</p> <p>3 percentage.</p> <p>4 Q. Okay.</p> <p>5 A. But what I can say is when the point estimate is</p> <p>6 weak, like 1.8 or 1.1, the probability of unmeasured or</p> <p>7 residual confounding contributing to that is very, very</p> <p>8 high. If the relative risk hazard ratio was 20, I would</p> <p>9 say it's very, very unlikely.</p> <p>10 Q. How many things have a relative risk of 20?</p> <p>11 A. The pulmonary hypertension study that's in my</p> <p>12 report. I mean, that's a -- that's a case control study</p> <p>13 too that --</p> <p>14 Q. You're talking about the Oppenheim study?</p> <p>15 A. I can't remember the first -- but it's the</p> <p>16 Phenaphen study looking at pulmonary hypertension</p> <p>17 development. There's a clear dose response curve.</p> <p>18 There's an increase in the odds ratio to 6 that goes to</p> <p>19 23. That's pretty high. How common is that? It's not</p> <p>20 common, but when it's --</p> <p>21 Q. I wish I could have you in the Phenaphen</p>	<p style="text-align: right;">Page 237</p> <p>1 with coffee drinking. It's just that smoking is related</p> <p>2 to pancreatic cancer, and smoking is related to coffee</p> <p>3 drinkers.</p> <p>4 Q. One more study -- one more thing on O'Brien 2024</p> <p>5 is an editorial by Harris.</p> <p>6 Have you seen that?</p> <p>7 MS. PARFITT: 22.</p> <p>8 THE WITNESS: Yes.</p> <p>9 (Deposition Exhibit 22 was marked.)</p> <p>10 BY MR. TISI:</p> <p>11 Q. You don't refer to it in your study. I assume</p> <p>12 that's because you don't agree with it; true?</p> <p>13 A. No. That's not why I didn't include it.</p> <p>14 Q. Okay. Why didn't you include it? You included</p> <p>15 Gossett you included -- a discussion of Gossett which</p> <p>16 supported your opinion, but you didn't include -- you</p> <p>17 didn't include Harris which does not; true?</p> <p>18 A. I may have seen this after I turned in my</p> <p>19 report.</p> <p>20 Q. Okay. The very bottom of the first page, it</p> <p>21 says, "In this paper, even with misreporting of the</p>

<p style="text-align: right;">Page 238</p> <p>1 exposure, i.e., genital powder use, in half the cases, a    2 significant increase in ovarian cancer risk is still    3 observed, adding support to the plausibility of a true    4 association between genital powder use and ovarian    5 cancer risk."</p> <p>6 Do you disagree with that?</p> <p>7 A. Well, I mean, I don't know what they're    8 referring to, because if you look at figure 2,    9 section A, if there's a reduction by 50 percent, even if    10 you agree with the assumption of using the hazard ratio    11 of 1.82, the hazard ratios falls to be more consistent    12 with previous studies of 1.17. So I don't know what    13 they're referring to there.</p> <p>14 Q. Okay. Did you make any effort to figure that    15 out?</p> <p>16 A. Other than my interpretation of figure 2 and    17 what they say -- and, again, this is an editorial.</p> <p>18 Q. Next -- just like Gossett was?</p> <p>19 A. Well, I actually did further calculations than    20 in the Gossett study that -- I don't necessarily agree    21 with 100 percent sure of what's in that editorial.</p>	<p style="text-align: right;">Page 240</p> <p>1 A. I do.</p> <p>2 Q. And I asked you about that question before    3 looking at the table with breast cancer, ovarian cancer,    4 and uterine cancer.</p> <p>5 Do you disagree with what they're saying here,    6 that that mitigates against recall bias being the    7 explanation for what they saw?</p> <p>8 A. I do disagree with that.</p> <p>9 Q. Okay.</p> <p>10 A. I mean, recall bias is a -- a based on someone's    11 recollection that they were exposed to a -- to    12 something, an exposure, that they have a sense that that    13 causes an outcome. And there's nothing in the    14 literature or in the -- or in general conversation that    15 cosmetic talc and uterine cancer are associated.</p> <p>16 Q. One other study that you referred to is Chang,    17 and I want to ask you a couple questions about Chang.</p> <p>18 A. Sure.</p> <p>19 Q. You talk about that. Chang and supplemental    20 tables, which are -- I'm going to make this Exhibit    21 Number 23.</p>
<p style="text-align: right;">Page 239</p> <p>1 I think that -- that the power calculations    2 actually are more supportive of no causal association    3 than in the Gossett paper.</p> <p>4 Q. On page 2, it says on the left-hand side, the    5 lack of -- the very last sentence. It says, "The lack    6 of an association between genital talc powder use and    7 uterine cancer provides additional support that recall    8 bias does not fully explain the genital powder and    9 ovarian cancer association."</p> <p>10 I asked you that question before, looking at the    11 table. I assume you would disagree with these authors    12 on that point?</p> <p>13 A. I'm sorry. I just can't find the sentence that    14 you read.</p> <p>15 Q. Yeah. Last sentence. Last sentence on the    16 left-hand side paragraph on page 2. It says, "The lack    17 of an association between genital powder use and uterine    18 cancer provides additional support that a recall bias    19 does not explain the genital powder and ovarian cancer    20 association."</p> <p>21 Do you see that?</p>	<p style="text-align: right;">Page 241</p> <p>1 MR. BISHOP: 23.</p> <p>2 MR. TISI: These have to be put together. So --</p> <p>3 MS. PARFITT: Here, Chris.</p> <p>4 MR. TISI: These should be together.</p> <p>5 Here's your copy.</p> <p>6 THE WITNESS: Thanks.</p> <p>7 (Deposition Exhibit 23 was marked.)</p> <p>8 BY MR. TISI:</p> <p>9 Q. All right. This is a study you referred to, and    10 you indicate that there is a nonstatistically    11 significant hazard ratio of 1.06 with a confidence    12 interval of .91 to 1.24.</p> <p>13 Do you see that?</p> <p>14 A. I do, yes.</p> <p>15 Q. That's taken from one of the supplemental tables    16 that's in this study?</p> <p>17 A. I would have -- I don't have it memorized,    18 but -- I'd have to find it in there.</p> <p>19 Q. I'll help you with it.</p> <p>20 This is another study from the NIH researchers,    21 including Drs. O'Brien and Sandler; correct.</p>

<p style="text-align: right;">Page 242</p> <p>1 MR. BISHOP: Do you have an extra copy?      2 MR. TISI: I'm sorry.      3 MR. BISHOP: I thought I had one handy, but --      4 MR. TISI: I thought I gave it to you, but --      5 MR. BISHOP: Yeah, no problem.</p> <p>6 BY MR. TISI:</p> <p>7 Q. This is another study by the NIH authors,      8 O'Brien and Sandler; right?</p> <p>9 A. Both O'Brien and Sandler are coauthors. Yes.</p> <p>10 Q. And what was the purpose of this study?</p> <p>11 A. The title says "Use of Personal Care Product      12 Mixtures -- Personal Care Product Mixtures and Incident      13 Hormone Sensitive Cancers in the Sister Study, a      14 U.S.-wide Prospective Cohort."</p> <p>15 Q. Okay. So this is also data from the Sister      16 Study from Dr. O'Brien and Sandler; right?</p> <p>17 A. It's an analysis of data from the Sister Study,      18 and they are coauthors.</p> <p>19 Q. Now, one of the things that you talk about here      20 in your analysis of Chang is that there was a 1.06      21 relative risk. But that wasn't for overall use. That</p>	<p style="text-align: right;">Page 244</p> <p>1 A. Well, I don't have the Sister Study      2 questionnaire memorize, but it would be -- for a      3 categorical variable, it's the first category moving to      4 the next category.</p> <p>5 Q. And if one-frequency category applies --      6 involves one exposure, one use, like one use per week,      7 to get the risk of five use for week -- five days use,      8 you would have to multiply the 1.06; correct? Across      9 five days.</p> <p>10 A. And -- I'm not following you.</p> <p>11 Q. Well, you would have to multiply 1.06 times 1.06      12 times 1.06 if you went up five frequency categories;      13 right?</p> <p>14 A. No.</p> <p>15 Q. You wouldn't?</p> <p>16 A. No.</p> <p>17 Q. Okay.</p> <p>18 A. No. That's a -- that's a linear relationship.</p> <p>19 And so if you move from category zero to category one,      20 there's a 6 percent increase. If you move from      21 category one to category two, that's a 6 percent</p>
<p style="text-align: right;">Page 243</p> <p>1 was for what we call one-frequency category; right? I      2 can point you to the table, if you -- if it makes sense.</p> <p>3 A. If you could, because I don't have it memorized.</p> <p>4 Q. Yes. It's table S-5, and it's in the      5 supplemental tables that I provided you.</p> <p>6 Do you see the table? Are you in the right      7 place? I just want make sure you're in the right table.</p> <p>8 A. I believe I am. Yes.</p> <p>9 Q. And the title of the table is -- you've seen      10 this table before; right?</p> <p>11 A. S-5?</p> <p>12 Q. Yes.</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And the table says, "Scaled weights and      15 the association between one-frequency category increase      16 and the use of personal care products in breast,      17 ovarian, and uterine cancers from the underlying models      18 using quantile based G-computations."</p> <p>19 Do you see that?</p> <p>20 A. I do, yes.</p> <p>21 Q. What is a one-frequency category?</p>	<p style="text-align: right;">Page 245</p> <p>1 increase.</p> <p>2 Q. Okay. And how do you --</p> <p>3 A. But that doesn't mean that going from      4 category zero to category two is a 12 percent.</p> <p>5 Q. Okay. I didn't say it was 12 percent. I didn't      6 say you add them together. I said you multiply them?</p> <p>7 A. It certainly wouldn't be 36 percent.</p> <p>8 Q. Let's go to the study, page 7. They say on the      9 left-hand side, "We observed a positive association for      10 hygiene mixture in relationship to incident ovarian      11 cancer with douche and genital talc use -- a genital use      12 talc as the most important contributors to the mixtures,      13 which is consistent with both the Sister Study and other      14 studies."</p> <p>15 Do you see that?</p> <p>16 A. I do.</p> <p>17 Q. They are not saying that this study supports      18 that there's no increased risk with ovarian cancer, are      19 they? They're saying it's consistent with, among other      20 things, Wentzensen 2021 and Gonzalez 2016, which all      21 showed a positive increase; right?</p>

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<p>1 MR. BISHOP: Object to form. Compound.</p> <p>2 THE WITNESS: Can you ask that again? I'm not</p> <p>3 sure what you're asking me.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Yeah.</p> <p>6 They are saying that this -- the results of this</p> <p>7 study is consistent with an increase -- with an</p> <p>8 increased -- with an association due to talc and ovarian</p> <p>9 cancer, and they said when they said here on page 7.</p> <p>10 A. So I'm reading that this says, "We observed a</p> <p>11 positive association for the hygiene mixture in relation</p> <p>12 to incident ovarian cancer with douche and genital use</p> <p>13 talc as the most important contributors to the mixture,"</p> <p>14 which is consistent with the findings from both the</p> <p>15 Sister Study and other studies referencing the ones that</p> <p>16 you say.</p> <p>17 However, when you actually look at the single</p> <p>18 product versus the multiproduct, I have no idea how they</p> <p>19 come across as saying that talc use is a major</p> <p>20 contributor. It's clear that douching is a major</p> <p>21 contributor, but all the others are right along the line</p>	<p>1 PDQ, number -- you refer to the PDQ -- right? --</p> <p>2 in your report? In the most recent one,</p> <p>3 Exhibit Number 24.</p> <p>4 (Deposition Exhibit 24 was marked.)</p> <p>5 BY MR. TISI:</p> <p>6 Q. Just couple a couple questions on this.</p> <p>7 A. Sure.</p> <p>8 Q. This is the PDQ that you refer to in your</p> <p>9 report, on page 39 of your report.</p> <p>10 Do you see that?</p> <p>11 A. I do, yes.</p> <p>12 Q. Am I right? Okay.</p> <p>13 Just a couple questions on this. This NIH PDQ</p> <p>14 was dated what -- was dated March 6, 2024. I think you</p> <p>15 refer to that in your report.</p> <p>16 A. Yeah. It looks like mine is referenced as</p> <p>17 October 2023.</p> <p>18 Q. Okay. Well, I got a more recent one here. It's</p> <p>19 March of 2024.</p> <p>20 This is before the most recent studies in both</p> <p>21 Chang and O'Brien 2024; true?</p>
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<p>1 and cross the line of nonstatistical significance.</p> <p>2 Q. Well, they use these -- they use these two --</p> <p>3 these two as very closely associated, both talc use and</p> <p>4 for perineal use and douching; true?</p> <p>5 A. Can you ask that again?</p> <p>6 Q. They're very closely correlated?</p> <p>7 A. They have been correlated in previous studies.</p> <p>8 Yes. But -- however, in at least figure 4, there is --</p> <p>9 looking at the B section, hygiene, there's both single</p> <p>10 product and multiproduct use. And in both of those</p> <p>11 figures, it's really that douching stands out as the</p> <p>12 statistically significant covariate suggesting an</p> <p>13 association between -- because -- suggesting an</p> <p>14 association between this exposure and ovarian cancer.</p> <p>15 I don't know how they get talc out of that.</p> <p>16 (Leigh O'Dell, Esq. joined via Zoom.)</p> <p>17 BY MR. TISI:</p> <p>18 Q. So you disagree with the author's</p> <p>19 characterization of their own study again; right?</p> <p>20 A. Absolutely. I'm just looking at the figure.</p> <p>21 Q. Okay. No problem.</p>	<p>1 A. Certainly before O'Brien. Chang, I can't</p> <p>2 remember when that was actually published.</p> <p>3 Q. If there was -- you know, as somebody -- you</p> <p>4 would agree with me, would you not, that whether you</p> <p>5 agree with the conclusions of O'Brien 2024 or Chang 2024</p> <p>6 as well, those are significant studies of -- coming from</p> <p>7 cohort studies; correct?</p> <p>8 A. Both of them come from the Sister -- from data</p> <p>9 from the Sister Study.</p> <p>10 Q. And they're important -- they're both NIH</p> <p>11 studies; right? NIH Sister Study is an NIH cohort;</p> <p>12 true?</p> <p>13 A. That's my recollection. I don't specifically</p> <p>14 know what the funding is these days.</p> <p>15 Q. Do you -- you saw where the NIH actually listed,</p> <p>16 you know -- announced that this study was an</p> <p>17 important -- that O'Brien 2024 was an important --</p> <p>18 showed -- I'm paraphrasing now, but it was a confirmed</p> <p>19 association between talc and ovarian cancer; true?</p> <p>20 MR. BISHOP: I'm object to the paraphrasing.</p> <p>21 The document speaks for itself.</p>

<p style="text-align: right;">Page 250</p> <p>1 BY MR. TISI:</p> <p>2 Q. The documents speak for themselves.</p> <p>3 They characterized it as an important study</p> <p>4 enough that they issued a statement about it; true?</p> <p>5 MR. BISHOP: Same objection. Calls for</p> <p>6 speculation.</p> <p>7 THE WITNESS: I mean, I don't put announcements</p> <p>8 out through the NIH. I don't know what -- how they do</p> <p>9 that or why they do that.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Do you believe if you were writing a summary</p> <p>12 like, for example, the PDQ or writing a summary of the</p> <p>13 epidemiology for talc and ovarian cancer that you at</p> <p>14 least have to include O'Brien 2024 as part of the</p> <p>15 continuing evolution of the science?</p> <p>16 A. If I were writing a report or a statement that,</p> <p>17 you know, for an agency like the NIH or a review</p> <p>18 article, I would certainly include the O'Brien study and</p> <p>19 the Chang study in that.</p> <p>20 Q. Okay.</p> <p>21 A. But I would also describe the methods and --</p>	<p style="text-align: right;">Page 252</p> <p>1 Q. I didn't say it changed your opinion. I'm</p> <p>2 saying a discussion of those would be important to have</p> <p>3 in a document like this; true?</p> <p>4 MR. BISHOP: That is a different question. Go</p> <p>5 ahead.</p> <p>6 MR. TISI: Thank you. I appreciate that.</p> <p>7 THE WITNESS: I don't create a document like the</p> <p>8 PDQ. I don't know what goes in there. I've never done</p> <p>9 that. So I -- I can't really comment on that.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. Just a couple questions about asbestos.</p> <p>12 First of all, are you -- do you believe that all</p> <p>13 forms of asbestos are carcinogens? Whether it be</p> <p>14 chrysotile, tremolite, or any other form of asbestos,</p> <p>15 are they carcinogens? Are they considered to be human</p> <p>16 carcinogens?</p> <p>17 A. Given the right -- given a significant amount of</p> <p>18 exposure. Given exposure.</p> <p>19 Q. Do you -- have you heard the phrase that "there</p> <p>20 is no safe dose of asbestos"?</p> <p>21 A. I think so.</p>
<p style="text-align: right;">Page 251</p> <p>1 Q. Yeah. I'm not asking you to -- what you would</p> <p>2 say. I'm just saying it's an important contribution to</p> <p>3 the overall literature, so much so that you had to --</p> <p>4 you had to spend 24 hours understanding the study and</p> <p>5 including it in your expert report between -- before it</p> <p>6 was filed; true?</p> <p>7 A. Well, it's an important epidemiologic study that</p> <p>8 needs to be considered.</p> <p>9 Q. Right. And the -- as of now, the PDQ does not</p> <p>10 include any discussion of that study or even Chang;</p> <p>11 true?</p> <p>12 A. I haven't read this newest PDQ. I just have</p> <p>13 what's referenced on mine.</p> <p>14 Q. Yeah. I mean, I can -- I'll represent to you</p> <p>15 it's not referenced in here as well.</p> <p>16 In order to be accurate and complete and</p> <p>17 summarize the science, if it doesn't have reference to</p> <p>18 those studies, this PDQ would be out of date; true?</p> <p>19 A. Well, it depends. It depends if the science</p> <p>20 changed. And Chang doesn't change my opinion and</p> <p>21 neither does O'Brien.</p>	<p style="text-align: right;">Page 253</p> <p>1 Q. Okay. Do you know that the FDA has, as recent</p> <p>2 as, like, within the last month and a half, classified</p> <p>3 chrysotile as an ovarian carcinogen and included</p> <p>4 chrysotile that would be in talc mined from mines?</p> <p>5 A. Can you ask that again?</p> <p>6 Q. Yes.</p> <p>7 Do you understand than even within the last</p> <p>8 month or two that the EPA has categorized chrysotile as</p> <p>9 an ovarian carcinogen?</p> <p>10 Let's leave it at that. Do you understand that?</p> <p>11 A. So I'm not aware of the EPA's -- whether or not</p> <p>12 that's happened in the last month. I am aware of IARC</p> <p>13 and their classification of asbestos as an ovarian</p> <p>14 carcinogen.</p> <p>15 Q. That's not what I asked, though. I asked you</p> <p>16 about EPA.</p> <p>17 A. So I'm not aware of that.</p> <p>18 Q. Okay.</p> <p>19 A. But I will say that it depends on the exposure.</p> <p>20 Q. Okay. And would you ever allow any woman in</p> <p>21 your family to use powder that you thought was</p>

<p style="text-align: right;">Page 254</p> <p>1 contaminated with any dose of asbestos?</p> <p>2 MR. BISHOP: Objection. I'm sorry. Beyond the      3 scope of this witness.</p> <p>4 THE WITNESS: So as a physician and as a      5 pulmonologist and certainly as a father, we really don't      6 want anyone to be around asbestos. However, I do know      7 that there's -- there is an amount of asbestos in      8 ambient air, and that, in general, is felt to be      9 noncarcinogenic. We're all exposed to asbestos --</p> <p>10 BY MR. TISI:</p> <p>11 Q. That was not my question.</p> <p>12 MR. BISHOP: Let him finish.</p> <p>13 THE WITNESS: It just depends on the dosage.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Would you ever -- if somebody use talcum powder      16 for 30 years every day -- if you had somebody in your      17 family that was using talcum powder every day that had      18 asbestos in it, would you ever allow them to use it?</p> <p>19 MR. BISHOP: Object to form. Vague. I'm sorry.      20 Vague. Ambiguous. Overbroad.</p> <p>21 THE WITNESS: So, again, it would depend on the</p>	<p style="text-align: right;">Page 256</p> <p>1 Q. Would you necessarily expect to see pleural      2 thickening in women who had gotten ovarian cancer from      3 exposure to talc administered -- used for genital      4 dusting?</p> <p>5 A. So I would not expect to see pleural thickening      6 from someone who uses talc.</p> <p>7 Q. Talc with asbestos. Excuse me.</p> <p>8 A. So, again, what I would expect to see -- what      9 I was looking for was signs for asbestosis. And that      10 could either be in interstitial lung disease. It could      11 be pleural plaques, calcification. Could be pleural      12 thickening. Could be mesothelioma from asbestos.</p> <p>13 Pleural plaques can happen -- can occur with      14 much lower doses of asbestos than, say, mesothelioma.</p> <p>15 Q. Okay. You've not looked at the ovarian tissue      16 for any of these women, have you?</p> <p>17 A. I'm not a pathologist.</p> <p>18 Q. You have not looked at even the results from      19 pathology, have you?</p> <p>20 A. I did look at the results of -- because I was      21 curious. I just can't remember which specific cases</p>
<p style="text-align: right;">Page 255</p> <p>1 theoretical concentration of asbestos in there. And      2 there have been -- there was an FDA analysis of this,      3 and there have been at least one paper looking at the      4 potential lifetime exposure to asbestos using Baby      5 Powder with various different scenarios over the      6 lifetime.</p> <p>7 And given the FDA's worst case scenario      8 of .1 percent of asbestos over a 70-year lifetime, that      9 estimation is less than what one would be exposed to      10 asbestos from breathing air.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Let me ask you this: Do you think -- but the      13 numbers you --</p> <p>14 You have provided opinions in this case that you      15 looked at the chest x-rays of the plaintiffs involved in      16 these bellwether trials; true?</p> <p>17 A. Radiology. Yes.</p> <p>18 Q. Radiology.</p> <p>19 You understand that these are all ovarian cancer      20 cases; correct?</p> <p>21 A. That's correct.</p>	<p style="text-align: right;">Page 257</p> <p>1 that I looked at. But just curious as to what the      2 diagnosis was.</p> <p>3 Q. Okay. But you're not going to be offering      4 opinions relating to whether or not they had changes in      5 their ovaries related to exposure to, among other      6 things, asbestos or fibrous talc or anything else; true?</p> <p>7 A. I would rely on a pathologist, because I'm not a      8 pathologist.</p> <p>9 Q. Okay. Do you have any opinions on Carl and      10 Balderrama that are case-specific?</p> <p>11 A. Other than that I don't find any markers of      12 asbestos in the radiology.</p> <p>13 Q. I mean, is that even part of the differential      14 for ovarian cancer?</p> <p>15 A. Well, if we're talking about -- if we're talking      16 specifically about the potential for asbestos to be in      17 the cosmetic talcum powder that's been used and one can      18 develop pleural plaques with much less exposure to      19 asbestos than, say, a mesothelioma, then yes. And I'm      20 not seeing any markers of asbestos-related disease.</p> <p>21 Q. Do you ever -- in any of the studies that you</p>

<p style="text-align: right;">Page 258</p> <p>1 looked at -- and you talked about the studies that you      2 looked at, the miners or millers or anything like that.      3 With respect to ovarian cancer, did they even look for      4 changes in the lung for the purpose of deciding whether      5 or not they were exposed to talc through genital      6 dusting?</p> <p>7 MR. BISHOP: I'm sorry. Object. Vague.</p> <p>8 Ambiguous.</p> <p>9 THE WITNESS: Can you ask that -- I'm just not      10 sure I understand that question.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Yeah, no. That's fine. It's a confusing      13 concept.</p> <p>14 Do you know of any study which used radiology      15 scans as a surrogate for exposure to talcum powder for      16 the purpose of assessing ovarian cancer relating to      17 asbestos? I meant to say asbestos. Let me rephrase the      18 question.</p> <p>19 In any asbestos study that you've seen, have you      20 ever seen any of the researchers use lung radiology      21 films as a surrogate for exposure to asbestos in their</p>	<p style="text-align: right;">Page 260</p> <p>1 A. But -- so --</p> <p>2 Q. I mean, yes, the answer will be "no"?</p> <p>3 A. The answer to that is no.</p> <p>4 Q. Okay. So can you think of any study that would      5 support your use of lung radiology films to determine      6 whether or not a person had been exposed to asbestos      7 genetically?</p> <p>8 A. I -- I can't think of an epidemiologic study      9 where one is having radiology of the chest done to look      10 at an exposure when the outcome is ovarian cancer.</p> <p>11 Q. That's my point.</p> <p>12 And that's what you're doing here; right?</p> <p>13 A. It is. Because --</p> <p>14 Q. Okay.</p> <p>15 A. -- because the issue is whether or not there's a      16 significant amount of asbestos exposure.</p> <p>17 Q. Okay. If you give me a moment, I want to look      18 at my notes and I'm going to try to finish up here, but      19 I want to speak to my colleague here.</p> <p>20 A. Sure.</p> <p>21 (Off the record.)</p>
<p style="text-align: right;">Page 259</p> <p>1 ovaries?</p> <p>2 A. So in the miners and millers studies, the      3 majority of the subjects that were followed in those      4 cohorts were men. The radiology that was done in some      5 of the studies was mainly to look for -- to assess      6 whether or not one would have lung disease.</p> <p>7 And so for some of the studies that did look at      8 radiology when there was a higher level exposure to      9 talc, either in the mine or the mill, those folks      10 developed pneumoconiosis, so interstitial lung disease.</p> <p>11 Q. Okay.</p> <p>12 A. And that's --</p> <p>13 Q. But my question was: Did they ever use      14 radiology of the lungs in order -- in any way to try to      15 figure out whether or not they had asbestos-induced      16 ovarian cancer?</p> <p>17 A. Well, again, the majority of the workers were      18 men --</p> <p>19 Q. Were men. Right.</p> <p>20 A. -- were men in that study.</p> <p>21 Q. So the answer to my question would be "no"?</p>	<p style="text-align: right;">Page 261</p> <p>1 BY MR. TISI:</p> <p>2 Q. I'd like to go back -- if we would, go back to      3 the Chang study. And I was asking you about the      4 extrapolating out using the one-frequency category and      5 using that to account for longer term or greater      6 exposure.</p> <p>7 Do you remember those questions?</p> <p>8 A. That's correct.</p> <p>9 Q. The authors actually address that question in      10 the study.</p> <p>11 Do you recall that?</p> <p>12 A. Not specifically in paragraphs, but perhaps you      13 could show me what you're referring to.</p> <p>14 Q. Well, they do address it in the paragraphs. If      15 you go to the last paragraph of the study.</p> <p>16 MS. PARFITT: Do you have a page number, Bruce?</p> <p>17 MR. TISI: Page 14.</p> <p>18 BY MR. TISI:</p> <p>19 Q. If you read that paragraph.</p> <p>20 A. This -- the last paragraph of the paper?</p> <p>21 Q. Yeah. Let me read what I'm referring to and ask</p>

<p style="text-align: right;">Page 262</p> <p>1 you to comment on it.</p> <p>2 It says, "Although the observed effects of a</p> <p>3 one-frequency level increase was modest in magnitude,</p> <p>4 the impact would be more substantial when comparing the</p> <p>5 most frequent users with never users. For example, in</p> <p>6 8 percent higher hazard post-menopausal breast cancer</p> <p>7 for a one-category level increase in the beauty mixture</p> <p>8 could also -- could translate to an approximate</p> <p>9 36 percent higher hazard for the most frequent users</p> <p>10 compared to never users."</p> <p>11 Do you see?</p> <p>12 A. I do see that.</p> <p>13 Q. And that's the concept that -- of -- that I was</p> <p>14 talking about with that study -- with that chart that</p> <p>15 talked about talc use. You have to multiply them to get</p> <p>16 a more frequent use. Am I -- to get a more -- for</p> <p>17 people who use frequent -- talc frequently; true?</p> <p>18 A. Only if there's a linear relationship.</p> <p>19 Q. Okay. So you agree or disagree with their</p> <p>20 assessment here about how you deal with more frequent</p> <p>21 users as opposed to casual users?</p>	<p style="text-align: right;">Page 264</p> <p>1 Q. Yeah?</p> <p>2 A. That's -- that's a firm.</p> <p>3 Q. Oh, is that you? Okay.</p> <p>4 A. Yeah.</p> <p>5 MR. TISI: Okay. I did not know that was the</p> <p>6 name of your law firm, so now I get it.</p> <p>7 All right. I'm going to have marked -- are</p> <p>8 these related, Michelle.</p> <p>9 MS. PARFITT: Yes.</p> <p>10 MR. TISI: It'll make it a lot easiest if I let</p> <p>11 Michelle deal with this because she looked at this. Do</p> <p>12 you mind her asking these questions?</p> <p>13 MR. BISHOP: I don't mind. See how reasonable I</p> <p>14 am.</p> <p>15 MR. TISI: You are just a peach. You are,</p> <p>16 actually.</p> <p>17 (Off the record.)</p> <p>18 MR. TISI: All right. I'm going to mark them.</p> <p>19 And these are all copies --</p> <p>20 MS. PARFITT: I was going to hand them out.</p> <p>21 MR. TISI: Yeah. Why don't you do it? Because</p>
<p style="text-align: right;">Page 263</p> <p>1 A. I mean, it says we could. It's possible but</p> <p>2 it's certainly not possible and it just depends on the</p> <p>3 dose relationship.</p> <p>4 Q. Okay. And you don't think that there's any?</p> <p>5 A. There's -- there's nothing presented that there</p> <p>6 is.</p> <p>7 Q. Okay. All right. Can we get -- I'd like to</p> <p>8 mark the invoices as an exhibit and ask you about that.</p> <p>9 MR. BISHOP: I think it would be Exhibit 25.</p> <p>10 MR. TISI: Yeah. Except I'm looking for them.</p> <p>11 Did I give him a copy?</p> <p>12 THE WITNESS: Let me look.</p> <p>13 MR. BISHOP: I thought you put them down that</p> <p>14 way.</p> <p>15 THE WITNESS: I don't know that you gave me the</p> <p>16 invoices.</p> <p>17 MS. PARFITT: You are good. Bruce, you are all</p> <p>18 right.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Oh, yeah. What is Willcox, by the way?</p> <p>21 A. Willcox Savage?</p>	<p style="text-align: right;">Page 265</p> <p>1 I didn't look at these.</p> <p>2 (Deposition Exhibit 25 was marked.)</p> <p>3 MS. PARFITT: Okay. I just have a couple</p> <p>4 questions.</p> <p>5 THE WITNESS: Sure.</p> <p>6 EXAMINATION BY MS. PARFITT:</p> <p>7 Q. We earlier marked your invoice as -- I believe</p> <p>8 they were exhibit -- or have we not done that?</p> <p>9 MR. TISI: We didn't mark those.</p> <p>10 MS. PARFITT: So they're now Exhibit 25.</p> <p>11 BY MS. PARFITT:</p> <p>12 Q. Before I actually hand you exhibits, it appears</p> <p>13 that we have a stack of exhibits and invoices for 2019,</p> <p>14 and we have a stack of invoices for the period of time</p> <p>15 2024.</p> <p>16 Do you have and can you make them available any</p> <p>17 and all invoices related to your talc-related work</p> <p>18 between 2016, when I believe you first got involved in</p> <p>19 this litigation, and 2019, when we first received</p> <p>20 invoices?</p> <p>21 MR. BISHOP: I'm just going to object. We'll be</p>

<p style="text-align: right;">Page 266</p> <p>1 happy to take the request under advisement.</p> <p>2 You can go ahead and answer.</p> <p>3 THE WITNESS: Sure.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q. Well, have you made those available in any other</p> <p>6 litigations, any state court litigations where you</p> <p>7 testified?</p> <p>8 A. Whatever I was required to make available was</p> <p>9 made available.</p> <p>10 MS. PARFITT: Okay. All right. Then we'll make</p> <p>11 a request for any and all invoices between 2016 and 2019</p> <p>12 related to Dr. Merlo's talc-related work.</p> <p>13 Similarly, there is absence of invoices between</p> <p>14 2019 and 2024.</p> <p>15 It looks like you picked up invoicing starting</p> <p>16 on January 31, '24. Similarly, we will make a request</p> <p>17 for production of invoices for talc-related work by</p> <p>18 Dr. Merlo between -- the last one I have is 5/31/19</p> <p>19 through January 31st, '24.</p> <p>20 THE WITNESS: That's --</p> <p>21</p>	<p style="text-align: right;">Page 268</p> <p>1 and not that, for example?</p> <p>2 A. That's correct.</p> <p>3 MR. TISI: Okay. All right. I believe that --</p> <p>4 unless we can finish up this exhibit with the --</p> <p>5 MS. PARFITT: Well, let's straighten up the</p> <p>6 exhibits. We have copies of the invoices, Bruce, for</p> <p>7 you as well.</p> <p>8 MR. TISI: Yeah. We'll do that as well. Okay.</p> <p>9 I don't have any other questions. Thank you.</p> <p>10 Do you have any questions?</p> <p>11 MR. BISHOP: I just had one follow-up.</p> <p>12 EXAMINATION BY MR. BISHOP:</p> <p>13 Q. Just so invoices are clear, do you have an</p> <p>14 hourly rate that you charge, and is it different than</p> <p>15 the hourly rate that the agency that helps you with the</p> <p>16 administration --</p> <p>17 A. I charge -- I charge \$450 an hour. When I see</p> <p>18 the invoice, it sometimes says \$540 an hour. There's an</p> <p>19 administrative fee that's, my understanding, is tacked</p> <p>20 on to that, but this is my -- this is my fee schedule,</p> <p>21 if you'd like that.</p>
<p style="text-align: right;">Page 267</p> <p>1 BY MS. PARFITT:</p> <p>2 Q. Lastly, the last invoice we received was one for</p> <p>3 4/30/24 in the amount of \$8,474.14.</p> <p>4 What do you estimate the number of hours that</p> <p>5 you've spent in this case working on talc-related</p> <p>6 matters from 4/30/24 to today, which is June 14, 2024?</p> <p>7 A. I would say 30 to 40 hours.</p> <p>8 (Off the record.)</p> <p>9 EXAMINATION BY MR. TISI:</p> <p>10 Q. So let me just ask one other question that I --</p> <p>11 other than the case-specific opinions about your review</p> <p>12 of the radiology for the lungs, do you have any other</p> <p>13 testimony that you're prepared to give related to any of</p> <p>14 the individual plaintiffs in the MDL case or in the</p> <p>15 Carl and Balderrama cases?</p> <p>16 A. Just the case-specific radiology that I</p> <p>17 reviewed.</p> <p>18 Q. Okay. And so you are not giving case-specific</p> <p>19 causation opinions? In other words, you're not going to</p> <p>20 say that I've reviewed this person's medical records</p> <p>21 and, in my opinion, their ovarian cancer is due to this</p>	<p style="text-align: right;">Page 269</p> <p>1 MR. TISI: Actually, you -- let's mark your fee</p> <p>2 schedule. I'm sorry. Are you done?</p> <p>3 MR. BISHOP: Yeah. I'm done.</p> <p>4 MR. TISI: Yeah. Let me just mark your fee</p> <p>5 schedule. I meant to do that before. This is</p> <p>6 Exhibit Number 26.</p> <p>7 (Deposition Exhibit 26 was marked.)</p> <p>8 MS. PARFITT: Yes, yes.</p> <p>9 MR. TISI: Because I have a question about that,</p> <p>10 and I'd glad that you asked.</p> <p>11 EXAMINATION BY MR. TISI:</p> <p>12 Q. Here's the fee schedule for VeraMedica</p> <p>13 Institute.</p> <p>14 Do they do your billing?</p> <p>15 A. I hand -- I submit an invoice of hours and --</p> <p>16 just so I can keep track of it to them, and then they</p> <p>17 perform the billing and send that out.</p> <p>18 Q. And I asked you -- I looked at</p> <p>19 Exhibit Number 26, and there's -- and I asked you</p> <p>20 before, I think, generally, but let me ask specifically.</p> <p>21 Who is the staff epidemiologist? Do you know?</p>

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1	A. I have no idea.	1 delivery. Can we get a rough, though?
2	Q. Okay. Nurse practitioner?	2 MR. BISHOP: Yeah. We'd like a rough and then
3	A. I know that there are a couple nurse	3 regular delivery.
4	practitioners, but I don't know them.	4 (Off the record.)
5	Q. Associate scientist?	5 MR. BISHOP: On the record, Dr. Merlo, you have
6	A. I don't know.	6 a right to read and sign the transcript or you can waive
7	Q. Did any of these people, physicians' support	7 that right.
8	staff, help you in any way over the years other than	8 THE WITNESS: I would like to read and...
9	collating records and that kind of a thing?	9 MR. BISHOP: Okay.
10	A. I've only had people help me with billing and	10 (The deposition was concluded at 2:19 P.M.)
11	people help me personally with, say, photocopying	11
12	something and providing me a binder or giving me	12
13	radiology discs or things like that.	13
14	Q. Do you know if they made additional money beyond	14
15	what you billed, or do you know if -- is their money	15
16	that they get paid incorporated in your billing? Is	16
17	that what you were trying to suggest before? In other	17
18	words, does your hourly rate include a cut for these	18
19	guys?	19
20	A. My hour hourly rate is \$450 an hour.	20
21	Q. For you?	21
	Page 271	Page 273
1	A. For me. And if it's billed something more than	1 CERTIFICATE FOR READING AND SIGNING
2	that, that's for them. But I'm not involved in that.	2
3	Q. Do you have any ownership interest in	3 I hereby certify that I have read and
4	VeraMedica --	4 examined the within transcript and the same is a true
5	A. No, I don't.	5 and accurate record of the testimony given by me.
6	Q. -- institute?	6
7	Do you work with them in other areas of	7 Any additions or corrections that I feel
8	research?	8 are necessary I have listed on the separate ERRATA SHEET
9	A. Research, no. But the administrators do help me	9 enclosed, indicating the page and line number of each
10	with my calendar.	10 correction.
11	Q. How about -- you know, you've been involved in	11
12	litigation, as I saw from your litigation list.	12 _____
13	Do they help you in all your litigation work, or	13 WITNESS NAME
14	is it just talc-related litigation?	14
15	A. If -- if I am introduced to a client through	15 _____
16	them, then it would be with them. But, in general,	16 DATE
17	they're not helping me with other aspects of litigation.	17
18	MR. TISI: Okay. I have no other questions.	18
19	COURT REPORTER: Can you just place your	19
20	transcript orders on the record, please?	20
21	MR. TISI: We're just going to order it regular	21

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1	ERRATA SHEET
2	Case: Johnson & Johnson Talcum Powder Litigation
3	Witness: Christian Merlo, M.D. Date: 6-14-24
4	PAGE/LINE SHOULD READ REASON FOR CHANGE
5	_____
6	_____
7	_____
8	_____
9	_____
10	_____
11	_____
12	_____
13	_____
14	_____
15	_____
16	_____
17	_____
18	_____
19	_____
20	_____
21	_____
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1	STATE OF MARYLAND
2	I, Faith Kelchaw, a Notary Public of the
3	State of Maryland, do hereby certify that the within
4	named deponent, after having been duly sworn by me, was
5	interrogated by counsel.
6	I further certify that the examination was
7	recorded stenographically by me and that this transcript
8	is a true record of the proceedings.
9	I further certify I am not of counsel to
10	any of the parties, nor an employee of counsel, nor
11	related to any of the parties, nor in any way interested
12	in the outcome of this action as witness my hand and
13	notarial seal this 26th day of June, 2024.
14	
15	_____
16	Faith Kelchaw, Notary Public
17	
18	My commission expires October 1, 2027.
19	
20	
21	

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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